

# Exhibit 2

1           IN THE UNITED STATES DISTRICT COURT  
2                   FOR THE DISTRICT OF NEW JERSEY  
3                   CAMDEN VICINAGE

- - -

4   IN RE: VALSARTAN,                   : MDL NO. 2875  
5   LOSARTAN, AND IRBESARTAN: CIVIL ACTION NO.  
6   PRODUCTS LIABILITY               : 19-2875  
7   LITIGATION                       : (RBK/JS)

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8   THIS DOCUMENT APPLIES           : HONORABLE  
9   TO ALL CASES                     : ROBERT B. KUGLER

- - -

10                   FEBRUARY 8, 2023

- - -

12                   Remote Videotape Deposition,  
13   taken via Zoom, of ALI AFNAN, Ph.D.,  
14   commencing at 9:23 a.m., on the above  
15   date, before Amanda Maslynsky-Miller,  
16   Realtime Reporter and Certified Court  
17   Reporter in and for the State of New  
18   Jersey.  
19

- - -

20  
21                   GOLKOW LITIGATION SERVICES, INC.  
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1 APPEARANCES: (Continued)	1
2	2 E X H I B I T S
3	3 - - -
4	4
5 HINSHAW & CULBERTSON LLP	5 NO. DESCRIPTION PAGE
6 BY: GEOFFREY M. COAN, ESQUIRE	6 Afnan-6 No Bates
7 53 State Street	7 Concise International
8 27th Floor	8 Document 31 121
9 Boston, Massachusetts 02109	9 Afnan-7 No Bates
10 (617) 213-7045	10 Dimethylformamide: Purification,
11 gcoan@hinshawlaw.com	11 Tests for Purity and
12 Representing Sciegen Pharmaceutical	12 Physical Properties 129
13	13 Afnan-8 No Bates
14	14 4/1/15 General Notices
15	15 and Requirements 181
16	16 Afnan-9 ZHP00190573-0574
17	17 Notice on the Results of
18	18 the Report of the Preliminary
19	19 Investigation on the Formation
20	20 of Unknown Impurities
21	21 Resulting from the Sodium
22	22 Azide Quenching in Crude
23	23 Irbesartan 221
24	24 Afnan-10 No Bates
	25 FDA Statement on the FDA's
	26 Ongoing Investigation Into
	27 Valsartan and ARB Class
	28 Impurities and the Agency's
	29 Steps to Address the Root
	30 Causes of the Safety Issues 250
	31 Afnan-11 No Bates
	32 Exhibit B-Materials Reviewed
	33 and Considered (Amended and
	34 Supplemental) 269
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1	- - -		
2	DEPOSITION SUPPORT INDEX		
3	- - -		
4			
5	Direction to Witness Not to Answer		
6	Page Line    Page Line    Page Line		
7	149    21		
8			
9			
10	Request for Production of Documents		
11	Page Line    Page Line    Page Line		
12	None		
13			
14			
15	Stipulations		
16	Page Line    Page Line    Page Line		
17	11    1		
18			
19			
20	Question Marked		
21	Page Line    Page Line    Page Line		
22	None		
23			
24			

Page 11			
1	- - -		
2	(It is hereby stipulated and		
3	agreed by and among counsel that		
4	sealing, filing and certification		
5	are waived; and that all		
6	objections, except as to the form		
7	of the question, will be reserved		
8	until the time of trial.)		
9	- - -		
10	VIDEO TECHNICIAN: Good		
11	morning. We are now on the		
12	record. My name is Phillip Todd,		
13	I'm a videographer for Golkow		
14	Litigation Services. Today's date		
15	is February 8th, 2023, and the		
16	time is 9:32 a.m.		
17	This remote video deposition		
18	is being held in the matter of		
19	Valsartan, Losartan and Irbesartan		
20	Products Liability Litigation in		
21	the United States District Court,		
22	District of New Jersey. The		
23	deponent is Dr. Ali Afnan.		
24	All parties to this		

Page 12			
1	deposition are appearing remotely		
2	and have agreed to the witness		
3	being sworn in remotely.		
4	Due to the nature of remote		
5	reporting, please pause briefly		
6	before speaking to ensure all		
7	parties are heard completely.		
8	Counsel's appearances will		
9	be noted on stenographic record.		
10	The court reporter, Amanda Miller,		
11	will now swear in the witness.		
12	- - -		
13	ALI AFNAN, Ph.D., after		
14	having been duly sworn, was		
15	examined and testified as follows:		
16	- - -		
17	EXAMINATION		
18	- - -		
19	BY MR. SLATER:		
20	Q. Good morning, Dr. Afnan.		
21	A. Good morning.		
22	Q. I'm Adam Slater, I'm going		
23	to take your deposition. How are you?		
24	A. I'm good. Thank you very		

Page 13			
1	much.		
2	Q. Great. Have you been		
3	deposed before?		
4	A. No.		
5	Q. You understand you must tell		
6	the truth in response to every question		
7	you're asked today?		
8	A. Yes.		
9	Q. If you're asked a question		
10	and you don't understand, for any reason,		
11	and you don't feel you can answer it		
12	truthfully or correctly, please tell the		
13	questioner and we'll refine the question		
14	so that you can understand it and that		
15	way you can then answer it, okay?		
16	A. Will do.		
17	Q. If counsel objects, let the		
18	counsel say whatever they need to say,		
19	and then you'll most likely be told to go		
20	ahead and answer.		
21	But wait until the objection		
22	is stated, okay?		
23	A. Thank you.		
24	Q. When did you first become		

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1 aware that valsartan manufactured by ZHP  
2 contained NDMA and NDEA?  
3 A. I think the very first time  
4 I became aware of it when -- is when I  
5 was approached to act as an expert  
6 witness.  
7 Q. What was that date?  
8 A. Sometime early October. I  
9 don't have the exact date.  
10 Q. Before that date, you were  
11 not aware of the fact that the valsartan  
12 manufactured by ZHP contained NDMA and  
13 NDEA?  
14 A. I -- no.  
15 Q. Were you aware of the recall  
16 of valsartan before that time that you  
17 were first approached for this case?  
18 A. No.  
19 Q. Had you ever heard of NDMA  
20 before you were approached regarding this  
21 case?  
22 A. I had heard of nitrosamines,  
23 yes.  
24 Q. In what context?

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1 A. Discussions with  
2 ex-colleagues about presence of NDMA in  
3 certain products, but not specific to  
4 which product.  
5 Q. When was that? Are you  
6 talking about before you were retained in  
7 this case?  
8 A. It's before I was retained  
9 in this case, yes.  
10 Q. And what was the context  
11 where you spoke to colleagues about NDMA?  
12 A. It was just that, you know,  
13 NDMA was present in certain products.  
14 Again, not specifically mentioned, except  
15 that it was in Metformin, because both of  
16 us were taking Metformin at that time.  
17 Q. And who was this colleague  
18 that you spoke to about this?  
19 A. It's -- it was actually at  
20 lunch with a group of ex-colleagues who  
21 are pharma executives or pharma employees  
22 and FDA employees.  
23 Q. So you were at a lunch where  
24 people from the FDA and people from

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1 pharma were having lunch together?  
2 A. No. As I said, it's  
3 ex-colleagues. It's a group of us who  
4 have retired, who have left FDA. We were  
5 meeting -- we meet every now and then.  
6 Q. You said they were ex --  
7 I'll rephrase.  
8 You said they were pharmacy  
9 executives. Did they also work at the  
10 FDA, those same people?  
11 A. No, no, no. They were not  
12 executives, they were employees of  
13 pharma, who have retired from pharma, and  
14 also ex-FDA employees; people that I used  
15 to work with.  
16 Q. So that was just an informal  
17 conversation at a lunch?  
18 A. That was purely an informal,  
19 by the way, have you heard of, yes.  
20 Q. When did that occur?  
21 A. Maybe summer of last year.  
22 Q. Summer of 2022?  
23 A. No, I don't remember the  
24 exact date. I'm just saying maybe summer

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1 of 2022.  
2 Q. You said summer of last  
3 year, that's why I asked --  
4 A. Yes.  
5 Q. -- if it was 2022.  
6 A. Yes.  
7 Q. If I understand correctly,  
8 in your work that you had done before you  
9 were approached for this case, you never  
10 specifically addressed nitrosamines, NDMA  
11 or NDEA; is that correct?  
12 A. Correct.  
13 MR. SLATER: Let's mark as  
14 Exhibit-1 the response to the  
15 deposition notice.  
16 - - -  
17 (Whereupon, Exhibit Afnan-1,  
18 No Bates, Defendants' Responses  
19 and Objections to Plaintiffs'  
20 Notice to Take Videotaped  
21 Deposition (ECF NO. 2258), was  
22 marked for identification.)  
23 - - -  
24 MR. SLATER: We can put that



1 on the screen.

2 MS. DAVIDSON: So I just  
3 want to make sure I understand.  
4 Are we going to be having that for  
5 everyone to see on the screen?

6 MR. SLATER: That's why I  
7 said put it on the screen.

8 MS. DAVIDSON: Just the  
9 other day you had a different  
10 approach you wanted to take, so I  
11 wanted to make sure I understood.

12 BY MR. SLATER:

13 Q. Doctor, do you see the  
14 exhibit -- the document we put up as  
15 Exhibit-1 on the screen?

16 A. Yes.

17 Q. Have you seen this document  
18 before?

19 A. If you scroll down, I will  
20 be able to tell you yes or no. I see  
21 only the top of the page.

22 Thank you.

23 Q. You can see now the first  
24 page. It's titled, Defendants' Responses

1 and Objections to Plaintiffs' Notice to  
2 Take Videotape Deposition.

3 A. Yes.

4 Q. Have you seen this document  
5 before?

6 A. Yes.

7 Q. Did you see the deposition  
8 notice?

9 A. I think so, yes.

10 MS. DAVIDSON: I think Ali,  
11 not being a lawyer, might not know  
12 what a deposition notice is. So  
13 if you want to ask if he's seen  
14 it, I suggest you show it to him.

15 MR. SLATER: That's all  
16 right. He just said he saw it.

17 THE WITNESS: No, I -- this  
18 is what I have seen.

19 BY MR. SLATER:

20 Q. Great. The questions are  
21 all on this, too. So we're good.

22 Okay. Did you go through  
23 each of the requests and attempt to  
24 provide the documents that were requested

1 in the deposition notice to the lawyers  
2 who hired you?

3 A. Yes.

4 MS. DAVIDSON: Dr. Afnan, I  
5 wanted to object to that question,  
6 and you did not give me time. So  
7 please make sure when Adam asks  
8 you a question, I know Adam talks  
9 very fast, and that encourages  
10 everyone around him to talk very  
11 fast, but it doesn't give -- I am  
12 not fast. It doesn't give me time  
13 to object.

14 So I do object to that  
15 question.

16 And please make sure that  
17 you allow me time in this  
18 deposition to object.

19 THE WITNESS: Sure. Sorry.  
20 Will do.

21 MR. SLATER: Chris, let's go  
22 to the end, to Number 17, please.  
23 Maybe we can make it a little  
24 bigger. Perfect.

1 BY MR. SLATER:

2 Q. Looking at Number 17, it  
3 requested, Any cGMP guidance, rule,  
4 protocol or procedure, drafted in whole  
5 or in part by Dr. Afnan, related to the  
6 development or manufacture of API or  
7 finished dose and/or with regard to  
8 genotoxic or other impurities in API or  
9 finished dose.

10 Do you see that?

11 A. Yes, I see that.

12 Q. In response, we were told  
13 that you were involved in the development  
14 of FDA's process analytical technology  
15 guidance in -- dated 2003, process  
16 validation guidance 2011, and guidance  
17 for industry, Q8 pharmaceutical  
18 development, 2006, correct?

19 MS. DAVIDSON: Adam, I don't  
20 see that. Is that --

21 MR. SLATER: It's in the  
22 response in the first paragraph of  
23 the response that you guys wrote.

24 MS. DAVIDSON: Oh, I see

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1 where you are. If you can point  
2 to where you're reading on the  
3 page, it would be helpful.  
4 BY MR. SLATER:  
5 Q. Do you see where I just  
6 read, Doctor?  
7 A. What you -- yes, I do.  
8 Q. Did you ever draft, in whole  
9 or in part, any other guidances, rules,  
10 protocols or procedures related to the  
11 development or manufacture of API or  
12 finished dose and/or with regard to  
13 genotoxic or other impurities in API or  
14 finished dose?  
15 MS. DAVIDSON: Adam, if you  
16 could possibly talk a little  
17 slower. I can't --  
18 MR. SLATER: I'm sorry,  
19 I'm -- I'm doing the best I can.  
20 BY MR. SLATER:  
21 Q. Are there any others,  
22 Doctor?  
23 A. No.  
24 Q. Do you agree that cGMP is an

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1 obligation -- rephrase.  
2 Do you agree that compliance  
3 with cGMP is an obligation of a  
4 pharmaceutical manufacturer like ZHP?  
5 MS. DAVIDSON: Objection.  
6 BY MR. SLATER:  
7 Q. Yes or no?  
8 MS. DAVIDSON: I'm going to  
9 object to that question. If that  
10 was a second question, I'm  
11 objecting again. I think it's  
12 vague.  
13 BY MR. SLATER:  
14 Q. Can you answer the question,  
15 please, Doctor?  
16 A. So --  
17 MS. DAVIDSON: Adam, give  
18 him a minute. Come on.  
19 THE WITNESS: So cGMPs are a  
20 minimal requirement for operation  
21 which industry pharma companies  
22 are expected to be aware of and to  
23 apply to their processes and their  
24 practices.

Page 24

1 BY MR. SLATER:  
2 Q. Do you agree with me that  
3 ZHP was required to comply with cGMP at  
4 all times -- at all times in the  
5 development and manufacture of valsartan?  
6 MS. DAVIDSON: I'm going to  
7 object again. And, also, I  
8 believe it was asked and answered.  
9 THE WITNESS: I did actually  
10 answer it.  
11 BY MR. SLATER:  
12 Q. Yes or no, please.  
13 MS. DAVIDSON: Adam, you  
14 know very well that he's not  
15 required to give you yes or no.  
16 He's allowed to answer the  
17 question as he deems fit and to  
18 provide whatever context he thinks  
19 is necessary.  
20 If I understand this  
21 question, I believe we've been  
22 down this road in this MDL  
23 proceeding.  
24 BY MR. SLATER:

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1 Q. Please answer the question,  
2 Doctor.  
3 A. GMPs specify what needs to  
4 be done and not how the things are to be  
5 done in a pharma company; and ZHP adhered  
6 to the GMPs.  
7 Q. Now I'm going to ask the  
8 question again.  
9 I didn't ask you any of that  
10 other things that you're talking about.  
11 So our deposition will go much more  
12 smoothly if I ask you a direct question  
13 to just answer it directly and not talk  
14 about other things. So I would  
15 appreciate it if you could try to do  
16 that, please.  
17 Was ZHP required to comply  
18 with cGMPs at all times during the  
19 development and manufacture of the  
20 valsartan that they manufactured and  
21 sold?  
22 MS. DAVIDSON: I'm going to  
23 object again. At this point I  
24 think you're badgering the



<p style="text-align: right;">Page 26</p> <p>1 witness.</p> <p>2 THE WITNESS: So I have</p> <p>3 answered the question. And I</p> <p>4 can't not give a dimension to my</p> <p>5 response.</p> <p>6 However, if you say, were</p> <p>7 they required -- was ZHP required</p> <p>8 to apply it, the GMPs, my -- I</p> <p>9 have to make a lot of assessments</p> <p>10 to say -- to answer that question.</p> <p>11 Again, I'll repeat, GMPs are</p> <p>12 a list of what-to-dos, not</p> <p>13 how-to-dos, and ZHP adhered to the</p> <p>14 GMPs.</p> <p>15 BY MR. SLATER:</p> <p>16 Q. I didn't ask you if they</p> <p>17 adhered. I didn't ask you if it's a</p> <p>18 how-to. I didn't ask you any of those</p> <p>19 questions.</p> <p>20 So I thought this would be</p> <p>21 the easiest question of the deposition.</p> <p>22 So I'm going to try it again.</p> <p>23 Do you agree with me that</p> <p>24 ZHP was required to comply with cGMPs in</p>	<p style="text-align: right;">Page 28</p> <p>1 question to ask if ZHP was required to</p> <p>2 comply with cGMPs in the development and</p> <p>3 manufacture of valsartan; is that your</p> <p>4 testimony?</p> <p>5 MS. DAVIDSON: I'm sorry.</p> <p>6 Objection.</p> <p>7 BY MR. SLATER:</p> <p>8 Q. Please answer.</p> <p>9 A. So the --</p> <p>10 MS. DAVIDSON: Hold on.</p> <p>11 You're mischaracterizing this</p> <p>12 testimony. And, also, every time</p> <p>13 I object you then ask a second</p> <p>14 question so that I have to object</p> <p>15 again.</p> <p>16 So I suggest that after I</p> <p>17 object, Dr. Afnan knows that he's</p> <p>18 supposed to answer a question,</p> <p>19 unless I instruct him not to</p> <p>20 answer. So I don't think it's</p> <p>21 helpful to badger him after I</p> <p>22 object, pressuring him to answer</p> <p>23 the question. He knows there's a</p> <p>24 question pending.</p>
<p style="text-align: right;">Page 27</p> <p>1 the development and manufacture of the</p> <p>2 valsartan API that it manufactured?</p> <p>3 MS. DAVIDSON: Objection</p> <p>4 again. Asked and answered.</p> <p>5 Vague. And at this point,</p> <p>6 badgering the witness.</p> <p>7 BY MR. SLATER:</p> <p>8 Q. It's a yes-or-no question,</p> <p>9 Doctor.</p> <p>10 MS. DAVIDSON: Again, I</p> <p>11 believe I stated this two minutes</p> <p>12 ago, but I'll state it again. He</p> <p>13 is not required to answer yes or</p> <p>14 no if he does not feel that yes or</p> <p>15 no is an adequate answer to the</p> <p>16 question. There's no thought</p> <p>17 control here.</p> <p>18 I'm sorry, Dr. Afnan.</p> <p>19 THE WITNESS: A yes or no</p> <p>20 does not actually address the</p> <p>21 question. I think the question is</p> <p>22 vague.</p> <p>23 BY MR. SLATER:</p> <p>24 Q. You think it's a vague</p>	<p style="text-align: right;">Page 29</p> <p>1 And then it's unclear to me,</p> <p>2 when you badger him again, whether</p> <p>3 I need to object again for the</p> <p>4 record.</p> <p>5 Do you want the court</p> <p>6 reporter to read back the</p> <p>7 question, Dr. Afnan, since we</p> <p>8 distracted you with our</p> <p>9 back-and-forth?</p> <p>10 THE WITNESS: Yes, please.</p> <p>11 - - -</p> <p>12 (Whereupon, the court</p> <p>13 reporter read the following part</p> <p>14 of the record:</p> <p>15 "Question: You think it's</p> <p>16 a vague question to ask" --)</p> <p>17 - - -</p> <p>18 MR. SLATER: I'm just going</p> <p>19 to state for the record that I</p> <p>20 think that defense counsel is</p> <p>21 obstructing the deposition.</p> <p>22 I'm going to now continue.</p> <p>23 BY MR. SLATER:</p> <p>24 Q. Dr. Afnan, are you saying</p>

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1 that my question is vague when I ask you  
2 if ZHP was required to comply with cGMPs  
3 in the development and manufacture of  
4 valsartan?

5 MS. DAVIDSON: Wait a  
6 minute. Adam, are you taking back  
7 the last question that I'm having  
8 the court reporter read back?

9 MR. SLATER: I'm not  
10 going -- I'm not going to go  
11 back-and-forth with you. You're  
12 eating up my time already. I'm  
13 not doing this with you.

14 So I'm going to continue my  
15 deposition.

16 MS. DAVIDSON: So I assume  
17 that question was stricken.

18 BY MR. SLATER:

19 Q. Please answer.

20 A. The reason I believe your  
21 answer is vague is -- your question is  
22 vague is because this is not a simple yes  
23 or no. It depends what the definition of  
24 cGMPs are, because, as I said, cGMPs are

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1 a list of what-to-dos as stipulated by  
2 the Food and Drug Administration.

3 How those are effectively  
4 put into practice is done through the  
5 procedures of the firm.

6 Q. And when the firm, then,  
7 puts those principles into effect, those  
8 standard operating procedures and  
9 internal procedures become requirements  
10 under cGMP, correct?

11 MS. DAVIDSON: Objection.

12 THE WITNESS: That's a  
13 circular argument. They don't  
14 become requirements under cGMP,  
15 they become, effectively, the  
16 practicing standards of the firm.  
17 And the firm can change those as  
18 well. There is a procedure for  
19 changing those. They are not, you  
20 know, written once and for all.

21 BY MR. SLATER:

22 Q. How do you define cGMP?

23 A. It is the cGMPs are defined,  
24 for API drug manufacturers in Q7 -- ICH

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1 guidance Q7. For drug product  
2 manufacturers, it's defined in 210 and  
3 211 of the code of federal regulations.

4 Again, those are the  
5 what-to-dos and not the how-to-dos.

6 Q. The how-to-do is pursuant to  
7 internal standard operating procedures  
8 that are put into place by the firm; is  
9 that what you're telling me?

10 A. Yes.

11 Q. Are you saying that ZHP was  
12 only required to comply with its own  
13 internal standard operating procedures  
14 with regard to cGMP and was not required  
15 to comply with ICH or other outside  
16 sources of cGMP guidance?

17 MS. DAVIDSON: Objection.  
18 Mischaracterizes the witness's  
19 testimony.

20 THE WITNESS: That's not  
21 what I said.

22 BY MR. SLATER:

23 Q. At all times that --  
24 rephrase.

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1 At all times that ZHP  
2 developed and manufactured valsartan, ZHP  
3 was required to comply with both the  
4 outside standards for cGMP that applied  
5 to its manufacture and development of  
6 valsartan, as well as the internal  
7 protocols that had been implemented by  
8 ZHP, pursuant to those outside sources;  
9 would you agree with that statement?

10 A. Can you --

11 MS. DAVIDSON: Objection.

12 THE WITNESS: Can you tell  
13 me which outside standards,  
14 please?

15 BY MR. SLATER:

16 Q. For example, ICH Q7.

17 A. If you look at ICH Q7, on  
18 the first page of the text of the  
19 document, as well as every other  
20 guidance, FDA makes a statement that this  
21 guidance is not binding and that it is a  
22 recommendation and it's the current  
23 thinking of FDA regarding a topic.

24 Q. Please define for me which

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1 cGMP standards applied to ZHP in the  
2 development and manufacture of valsartan.  
3 Please list for me those sources of  
4 objective authority, whether internal or  
5 external to ZHP, which applied to them  
6 and to which they had to comply.  
7 MS. DAVIDSON: That was two  
8 questions.  
9 MR. SLATER: Great.  
10 BY MR. SLATER:  
11 Q. Please answer.  
12 MS. DAVIDSON: Which one,  
13 the first or second?  
14 MR. SLATER: I'm not going  
15 to -- I'm not going to banter with  
16 you.  
17 BY MR. SLATER:  
18 Q. Please answer the question.  
19 MS. DAVIDSON: I'm going to  
20 object. That was a compound  
21 question.  
22 I think that the rules of a  
23 deposition are you ask one  
24 question at a time, and there were

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1 two in there.  
2 BY MR. SLATER:  
3 Q. Please answer the question.  
4 A. Can you ask the question  
5 again, please?  
6 Q. Please list for me each  
7 source of -- rephrase.  
8 Please list for me each  
9 standard that applied to ZHP's  
10 development and manufacture of valsartan  
11 with regard to cGMP.  
12 I want to know what --  
13 the universe of what you believe applied  
14 to them that they had to adhere to is.  
15 MS. DAVIDSON: I'm going to  
16 object again. I think it  
17 actually, Adam, I think it's  
18 important for this deposition to  
19 understand, when you say ZHP, do  
20 you also mean its subs or are you  
21 specifically referring to ZHP?  
22 MR. SLATER: I don't even  
23 understand your question. I'm not  
24 going to go back-and-forth.

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1 BY MR. SLATER:  
2 Q. Please answer the question.  
3 A. I have here in front of me  
4 ICH Q7. Q7 is a guidance issued by  
5 FDA -- ICH and adopted by FDA. It's  
6 title is, Good Manufacturing Practice  
7 Guidance for Active Pharmaceutical  
8 Ingredients, Guidance for Industry,  
9 September 2016.  
10 On the very Page Number 1,  
11 which is after Page Number 4, 4 as in IV,  
12 it states, Good manufacturing practice  
13 guidance for active pharmaceutical  
14 ingredients. Guidance for industry.  
15 And there is a black box  
16 which says, This guidance represents the  
17 current thinking of the Food and Drug  
18 Administration on this topic. It does  
19 not establish any rights for any person  
20 and is not binding on FDA or the public.  
21 You can use an alternative approach if it  
22 satisfies the requirements of the  
23 applicable statutes and regulations.  
24 So --

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1 Q. Is that your complete answer  
2 to my question?  
3 A. You're asking me for --  
4 again, you know, this goes back to the  
5 very first question, one of the previous  
6 questions, of you saying specify the  
7 standards.  
8 My point is, the GMPs are a  
9 set of what-to-dos and not how-to-dos.  
10 Industry needs to follow the how-to-dos  
11 and those how-to-dos are based on -- for  
12 API manufacturers, are based on Q7, which  
13 ZHP followed and did.  
14 Q. I'd like you to list for  
15 me -- rephrase.  
16 Please list for me those  
17 cGMP standards, whether they are external  
18 to ZHP or internal to ZHP, such as  
19 standard operating procedures that  
20 applied to ZHP in its development and  
21 manufacture of valsartan.  
22 I need to know the list of  
23 what you believe they were required to  
24 comply with when they developed and

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1 manufactured the valsartan.  
2 Please answer the question.  
3 MS. DAVIDSON: Objection.  
4 Compound. Asked and answered.  
5 Vague.  
6 BY MR. SLATER:  
7 Q. I'm not asking you to read  
8 the standards to me. I'm asking for you  
9 to list them for me, please.  
10 A. So -- so if I'm going to  
11 list them, Mr. Slater, I would go to  
12 ICH Q7, okay; and I would go to the table  
13 of contents.  
14 Would you like me to list  
15 them for you?  
16 Q. I don't need you to list for  
17 me the table of contents.  
18 If you think that ICH Q7 was  
19 something that ZHP needed to comply with,  
20 per my question, you can say ICH Q7.  
21 I don't need you to read me  
22 the table of contents.  
23 A. The sections -- sorry.  
24 MS. DAVIDSON: Dr. Afnan,

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1 you've got to leave me time to  
2 object.  
3 Because I object to that. I  
4 don't even think it was a  
5 question.  
6 THE WITNESS: The current  
7 standard in industry, and as  
8 practiced by the regulators, is to  
9 have a quality system which is  
10 effectively defined through a  
11 guidance of FDA, which talks about  
12 quality systems.  
13 And it's defined -- or it's  
14 stipulated as what it needs to  
15 have in Q7. It requires,  
16 effectively, the Quality 7, the  
17 training of the personnel, the  
18 buildings and facilities, the  
19 process equipment, documentation  
20 and records, material management,  
21 production and in-process  
22 controls, packaging and  
23 identification labeling for APIs  
24 and intermediates, validating the

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1 lab controls, validation, change  
2 control, rejection of materials,  
3 complaints and recalls.  
4 Now, about the internal  
5 standards, that would be the list  
6 of ZHP's SOPs, which I do not  
7 have. That was beyond the scope  
8 of my agreement.  
9 BY MR. SLATER:  
10 Q. When you say "beyond the  
11 scope" of your agreement, what do you  
12 mean?  
13 A. Not agreement, my agreement.  
14 It was -- I was not tasked with assessing  
15 all the GMPs of ZHP.  
16 Q. Got it.  
17 MR. SLATER: We can take  
18 down the deposition notice. Let's  
19 put up as Exhibit --  
20 BY MR. SLATER:  
21 Q. Well, let me ask you,  
22 Doctor, do you have your report in front  
23 of you?  
24 A. I do.

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1 MR. SLATER: We have a  
2 December 23, 2022, report. For  
3 the record, we'll put it up on the  
4 screen just so everybody can see  
5 it. And it will be for the court  
6 reporter to have it. But that  
7 will be Exhibit-2.  
8 - - -  
9 (Whereupon, Exhibit Afnan-2,  
10 No Bates, 12/23/22 Expert Report  
11 of Ali Afnan, Ph.D., was marked  
12 for identification.)  
13 - - -  
14 BY MR. SLATER:  
15 Q. Doctor, subject to an e-mail  
16 that we got that had some corrections of  
17 a few things within the report, is this  
18 the only report -- well, rephrase. Let  
19 me ask it differently.  
20 Is this the only report  
21 you've written in this case?  
22 A. I -- the amended report was,  
23 I think, submitted on January 11, 2023.  
24 Q. Sorry. I had a malfunction

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1 here.  
2 Let me ask the question  
3 again.  
4 The December 23, 2022,  
5 report we have on the screen is the first  
6 report you wrote in this case, correct?  
7 A. Yes.  
8 Q. Did that contain all the  
9 opinions you had formed at the time that  
10 you authored that report?  
11 MS. DAVIDSON: Objection.  
12 THE WITNESS: Did it  
13 contain -- can you -- can you  
14 rephrase the question, please?  
15 BY MR. SLATER:  
16 Q. On the screen we have your  
17 December 23, 2022, report.  
18 A. Yes.  
19 Q. Did that report contain the  
20 opinions you had formed at the time that  
21 you signed that report on December 23,  
22 2022?  
23 A. Yes.  
24 MR. SLATER: Let's take that

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1 down and put up as Exhibit-3 the  
2 amended report now.  
3 - - -  
4 (Whereupon, Exhibit Afnan-3,  
5 No Bates, 1/11/23 Expert Report of  
6 Ali Afnan, Ph.D., was marked for  
7 identification.)  
8 - - -  
9 BY MR. SLATER:  
10 Q. Exhibit-3 is the January 11,  
11 2023, report.  
12 Is that the second report  
13 you wrote in this case?  
14 A. Yes.  
15 Q. Can you tell me what, if  
16 anything, is different between the  
17 January 11 report and the December 23,  
18 2022, report?  
19 I don't need you to find  
20 page numbers. If you can just tell me  
21 generally what you did with the report  
22 between those two dates.  
23 MS. DAVIDSON: Objection.  
24 BY MR. SLATER:

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1 Q. Let me ask the question  
2 differently.  
3 Why did you serve an amended  
4 report on January 11, 2023?  
5 A. I discovered typographical  
6 errors in it. And then also I came  
7 across a version of M7 which I had not  
8 referred to in my December 23 report, it  
9 was the earlier version of M7.  
10 Q. In your work outside of this  
11 case, did you ever apply M7 in any case,  
12 any situation?  
13 A. In my work I have -- during  
14 the development phase of working with  
15 some clients, I do look -- I have looked  
16 at M7.  
17 Q. What was the context?  
18 MS. DAVIDSON: Adam, before  
19 you go on.  
20 Dr. Afnan, as Adam has  
21 cautioned his witnesses, I know  
22 that some of your consulting work  
23 may be confidential. And you're  
24 not obligated to violate

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1 confidentiality of relationships  
2 or agreements with clients in  
3 order to respond to this  
4 deposition.  
5 So please keep that in mind  
6 when you're asked any questions  
7 about your consulting work.  
8 Thank you.  
9 THE WITNESS: Thank you.  
10 As I said, it was during  
11 drug development processes.  
12 BY MR. SLATER:  
13 Q. Was that API drug  
14 development process or finished dose drug  
15 development process?  
16 A. In both cases, it was a new  
17 drug, so it was both development of the  
18 API and also, then, development of the  
19 drug product.  
20 Q. When did that occur?  
21 A. Over the last five years. I  
22 don't have the exact dates.  
23 Q. Let's go back to Exhibit-2.  
24 Attached to Exhibit-2 is



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1 your C.V., curriculum vitae, correct?

2 A. Yes.

3 Q. You're currently the

4 president and founder of Step Change

5 Pharma, Inc.

6 What is that company?

7 A. It's a consulting company.

8 Q. What do you consult on?

9 A. Various projects all related

10 to pharma; from drug development, which

11 is a much lesser extent of my work, to

12 GMP remediation, manufacturing

13 enhancements.

14 Q. When you say drug

15 development is a lesser part of your

16 work, what do you mean by that?

17 A. I have -- I have, maybe, two

18 or three clients who work in that area.

19 Q. What does GMP remediation

20 mean?

21 A. Firms who have gotten into

22 trouble with FDA or the European Agency

23 or any of the others and need to

24 effectively remediate.

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1 Q. Did ZHP need to do GMP

2 remediation?

3 A. They got 483 obligations,

4 which they addressed. That's what I call

5 remediation.

6 Q. Have any of your clients

7 received FDA warning letters for which

8 you had to perform GMP remediation?

9 MS. DAVIDSON: Objection.

10 BY MR. SLATER:

11 Q. You can answer, Doctor.

12 A. Yes.

13 Q. How many times?

14 A. I don't recall. Truthfully,

15 I don't recall.

16 Q. Is it a good thing for a

17 pharmaceutical manufacturer to receive a

18 warning letter from the FDA? Does the

19 manufacturer like getting warning

20 letters? Is that something they like to

21 get?

22 MS. DAVIDSON: Objection.

23 That was three questions. Vague.

24 I think that's all.

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1 MR. SLATER: I'll ask it

2 again.

3 BY MR. SLATER:

4 Q. Do pharmaceutical

5 manufacturers hope to receive warning

6 letters from the FDA?

7 MS. DAVIDSON: Objection.

8 THE WITNESS: Pharma

9 manufacturers are in the business

10 of making a drug or drugs and

11 selling them, not receiving

12 warning letters.

13 BY MR. SLATER:

14 Q. That's -- I didn't ask you

15 what business they're in. I asked you a

16 simple question.

17 Is the answer yes or no?

18 MS. DAVIDSON: Objection.

19 Maybe rephrase the question.

20 MR. SLATER: I don't think I

21 need to.

22 BY MR. SLATER:

23 Q. Can you answer, please?

24 MS. DAVIDSON: Well, I'm

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1 objecting again.

2 THE WITNESS: The answer is

3 no, because that's why they engage

4 third parties to do the work to

5 help them.

6 BY MR. SLATER:

7 Q. What do you mean by that,

8 that's why they retain third parties to

9 do the work to help them?

10 I don't understand. What's

11 that mean?

12 A. They -- at times, firms work

13 with external parties like me, a GMP

14 remediation company, to assist them with

15 putting -- you know, correcting whatever

16 has been identified, partly -- yeah.

17 Q. ZHP received a warning

18 letter in November 2018, correct?

19 A. Yes.

20 Q. That letter -- rephrase.

21 That warning letter

22 identified violations of cGMPs, correct?

23 MS. DAVIDSON: Objection.

24 BY MR. SLATER:



1 Q. Can you answer the question,  
2 please?

3 MS. DAVIDSON: I believe the  
4 witness was thinking. And I do  
5 want to state for the record --

6 MR. SLATER: I think the  
7 problem is, Jessica, when you're  
8 objecting, he doesn't know if he's  
9 allowed to answer the question.

10 MS. DAVIDSON: No, I  
11 explained at the beginning of the  
12 deposition --

13 MR. SLATER: I don't want to  
14 argue with you. I'm not going to  
15 engage with you.

16 MS. DAVIDSON: Okay. I  
17 don't want to engage with you  
18 either, Adam.

19 But I want to point out that  
20 you had many witnesses last week  
21 who took up to five minutes to  
22 answering questions. We did not  
23 badger them or interrupt the  
24 deposition to address that. Many

1 of your witnesses took significant  
2 periods of time.

3 If Dr. Afnan is thinking, I  
4 don't think badgering him to  
5 answer more quickly is fair or  
6 appropriate deposition practice.

7 MR. SLATER: I disagree with  
8 everything you just said and I'm  
9 going to wait for the answer.

10 THE WITNESS: So a statement  
11 on the warning letter is actually  
12 boilerplate language which is on  
13 every warning letter which FDA  
14 issues.

15 BY MR. SLATER:

16 Q. The warning letter states,  
17 in part, This warning letter summarizes  
18 significant deviations from current good  
19 manufacturing practice, cGMP, for active  
20 pharmaceutical ingredients, API.

21 The letter says that, right?

22 MS. DAVIDSON: Objection.

23 If you're asking him to confirm  
24 the reading of a document,

1 obviously that document needs to  
2 be in front of him. I don't think  
3 Dr. Afnan memorized the warning  
4 letter or maybe he did.

5 MR. SLATER: Do you want to  
6 testify for him that he didn't  
7 memorize the warning letter or do  
8 you want to try to let him to  
9 answer the question?

10 MS. DAVIDSON: I don't know,  
11 maybe he did memorize it. My  
12 point is, if you're asking --

13 MR. SLATER: Why are you  
14 trying to block him from answering  
15 the question?

16 MS. DAVIDSON: I am not  
17 trying to block him from answering  
18 the question, Adam. As somebody  
19 who repeatedly told his witness  
20 last week to look at a document, I  
21 think this is kind of an ironic  
22 accusation.

23 If you want Dr. Afnan to  
24 testify as to whether you read a

1 document accurately, obviously he  
2 needs the document in front of  
3 him.

4 BY MR. SLATER:

5 Q. Doctor, can you answer the  
6 question, please?

7 A. I would appreciate,  
8 actually, if you could put it up.

9 Q. Okay. You said that the  
10 letter contained boilerplate language  
11 that's found in all warning letters.

12 Do you remember you said  
13 that a few moments ago?

14 A. Yes.

15 Q. What's the boilerplate  
16 language you were referring to?

17 A. If you put it up, I'll show  
18 you.

19 Q. Let's put it up.

20 MR. SLATER: This will be  
21 exhibit, what, 3? 4, okay.  
22 Exhibit-4 will be the warning  
23 letter.

24 - - -

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1 (Whereupon, Exhibit Afnan-4,  
2 PRINSTON00077339-7344, 11/29/18  
3 Letter, Godwin to Du, was marked  
4 for identification.)  
5 - - -  
6 THE WITNESS: If you would  
7 be kind enough to scroll down,  
8 please.  
9 So the boilerplate language  
10 is, This warning letter summarizes  
11 significant deviations from  
12 current good manufacturing  
13 practice, cGMP 4.  
14 And then the rest of it  
15 would be for whether it's testing,  
16 whether it's APIs, or whether it's  
17 for drug product.  
18 The next paragraph is also  
19 boilerplate language.  
20 BY MR. SLATER:  
21 Q. Does every manufacturer of  
22 pharmaceutical products receive a warning  
23 letter that contains the boilerplate  
24 language you just described every year?

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1 A. So if you can read the  
2 question back to me, because that was an  
3 interesting question.  
4 Q. Well, I'll ask it -- I'll  
5 ask it differently. Well, actually, I'll  
6 ask it again.  
7 Does every pharmaceutical  
8 manufacturer, under the jurisdiction of  
9 the FDA, receive a warning letter every  
10 year with regard to all products that  
11 they manufacture that contains the two  
12 boilerplate sections you just pointed out  
13 to me?  
14 MS. DAVIDSON: Objection.  
15 THE WITNESS: If a firm is  
16 inspected, and it's very rare that  
17 FDA inspects every year, if a firm  
18 is inspected and observations are  
19 given to it, the firm responds.  
20 FDA will then make a  
21 determination, based on the  
22 observations, the response and the  
23 EIR whether to issue a warning  
24 letter or not.

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1 Every warning letter that is  
2 issued has those two paragraphs in  
3 it.  
4 BY MR. SLATER:  
5 Q. The warning letter sent by  
6 the FDA to ZHP, dated November 29, 2018,  
7 identified what they described in their  
8 letter as significant deviations from  
9 current good manufacturing practice for  
10 active pharmaceutical ingredients.  
11 That's what the letter says,  
12 correct?  
13 A. That's what the letter says,  
14 yes.  
15 Q. The warning letter also  
16 states, Because your methods, facilities  
17 or controls for manufacturing,  
18 processing, packing or holding do not  
19 conform to cGMP, your API are adulterated  
20 within the meaning of Section  
21 501(a)(2)(B) of the Federal Food, Drug  
22 and Cosmetic Act, correct?  
23 That's what it says in the  
24 letter, correct?

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1 A. That's what it says in the  
2 letter.  
3 MR. SLATER: You can take  
4 the letter down.  
5 BY MR. SLATER:  
6 Q. When you were at the FDA,  
7 did you have any responsibility to  
8 oversee API manufacturing of drugs?  
9 MS. DAVIDSON: Objection.  
10 THE WITNESS: In my years at  
11 FDA, and the way FDA currently  
12 works, there is no individual  
13 person responsible for API  
14 manufacturing. It's effectively  
15 managed through either the review  
16 division or through ORA for  
17 inspection, but primarily through  
18 the review division.  
19 And, no, I was not solely  
20 individually responsible for API  
21 manufacturing.  
22 BY MR. SLATER:  
23 Q. When you were at the FDA,  
24 did you have any responsibility in

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1 connection with any matters focused on  
 2 API manufacturing of pharmaceutical drugs  
 3 at any time?  
 4 MS. DAVIDSON: Objection.  
 5 BY MR. SLATER:  
 6 Q. Let me ask the question  
 7 differently. I just want to make it  
 8 cleaner.  
 9 A. Yes.  
 10 Q. At the FDA -- I'm going to  
 11 ask it differently.  
 12 At the FDA, did you have  
 13 responsibility in any way, or involvement  
 14 in any way, with any matter involving the  
 15 manufacture of API?  
 16 A. So was I involved with the  
 17 review of API applications or  
 18 documentation? The answer is yes.  
 19 But your question is vague  
 20 in saying I was responsible solely for  
 21 manufacture of API.  
 22 Q. I never asked if you were  
 23 solely responsible. So the vague point  
 24 that you're concerned about, I never

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1 actually asked that.  
 2 A. My apologies.  
 3 Q. You don't have to apologize.  
 4 What I'm asking, in a broad  
 5 sense, is, what, if any, involvement you  
 6 ever had with any matter involving API  
 7 manufacture when you were at the FDA?  
 8 MS. DAVIDSON: Objection.  
 9 THE WITNESS: I believe I've  
 10 answered that.  
 11 BY MR. SLATER:  
 12 Q. Just to be clear, would you  
 13 please tell me what involvement you ever  
 14 had with any matter involving API  
 15 manufacturing?  
 16 A. I have been involved with  
 17 the review of API manufacturing  
 18 processes.  
 19 Q. In what context would you  
 20 have reviewed the processes? Would it  
 21 have been where you went out and did an  
 22 inspection? Would it have been review of  
 23 an application? Would you have reviewed  
 24 a document? Would you have had a

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1 conversation with someone?  
 2 Can you explain to me what  
 3 that involvement would have been?  
 4 A. The review --  
 5 MS. DAVIDSON: Whoa. You  
 6 got to give me a minute to object.  
 7 That was, like, seven  
 8 questions. So I'm not sure -- it  
 9 was super compound.  
 10 If you know which one to  
 11 answer, go ahead.  
 12 THE WITNESS: Which one was  
 13 I involved with? The review  
 14 process and approval process of  
 15 APIs in FDA is very -- complex is  
 16 the wrong word.  
 17 It's a team effort. So  
 18 there are multiple divisions,  
 19 multiple groups, who actually get  
 20 engaged in the review process.  
 21 The review process consists  
 22 of, for APIs, depending whether  
 23 it's a generic or whether it's a  
 24 brand, whether it's existing or

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1 whether it's new, it will  
 2 effectively be reviewed by  
 3 different multidisciplinary  
 4 groups.  
 5 And where I have been  
 6 involved was to look at the  
 7 manufacturing processes in  
 8 relation to APIs.  
 9 It is then reviewed. The  
 10 agency, the FDA, asks for an  
 11 inspection of the facility, if it  
 12 doesn't have enough information  
 13 about the GMP status of the  
 14 facility. And then it makes a  
 15 collective decision.  
 16 BY MR. SLATER:  
 17 Q. I didn't ask you what the  
 18 FDA does to oversee API. I asked what  
 19 involvement, if any, you've ever had when  
 20 you were at the FDA with any matter  
 21 involving API, what you did.  
 22 A. I answered that.  
 23 Q. I need you to tell me what  
 24 you did.

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1 MS. DAVIDSON: Objection.  
 2 THE WITNESS: I answered  
 3 that. I said I was involved with  
 4 the review of the application to  
 5 FDA.  
 6 BY MR. SLATER:  
 7 Q. When you say "review of the  
 8 application to FDA," what specific  
 9 application is that? Is there a name for  
 10 that application?  
 11 A. That comes as part of either  
 12 ANDA, NDA or DMF.  
 13 Q. And in your role, what would  
 14 your responsibility have been in looking  
 15 at those applications? What were you  
 16 looking for? What were you doing?  
 17 A. My role was to look at,  
 18 effectively, the manufacturing process,  
 19 the controls, what FDA calls chemistry  
 20 manufacturing and controls of the  
 21 processes.  
 22 Q. What were you looking for  
 23 when you were looking at that material?  
 24 A. Whether the process was

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1 feasible or not, whether the critical  
 2 process parameters which have been  
 3 identified correlated to the critical  
 4 quality attributes and how those  
 5 attributes were controlled, and whether  
 6 they met USD requirements or if those  
 7 were in-house specifications.  
 8 Q. Do you hold yourself out as  
 9 an expert in organic chemistry?  
 10 A. No, not as an expert in  
 11 organic chemistry. No.  
 12 Q. Are you holding yourself out  
 13 as an expert in FDA regulation of API and  
 14 finished drug products?  
 15 A. I have extensively worked in  
 16 the API and drug product domain.  
 17 Q. Do you hold yourself out as  
 18 an expert with regard to the  
 19 identification of genotoxic impurities in  
 20 drug substances?  
 21 MS. DAVIDSON: Objection.  
 22 THE WITNESS: That's  
 23 actually two questions. And I am  
 24 not a toxicologist, so I'm not one

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1 to determine genotoxicity of a  
 2 chemical compound.  
 3 BY MR. SLATER:  
 4 Q. When you worked at  
 5 AstraZeneca, were you involved in the  
 6 development or manufacture of API?  
 7 A. Yes.  
 8 Q. What was your responsibility  
 9 in that context?  
 10 A. Process control.  
 11 Q. What does that mean, process  
 12 control?  
 13 A. Controlling the  
 14 manufacturing process to end up with the  
 15 result that was determined as desirable.  
 16 Q. When you say to end up with  
 17 the result that was desired, what does  
 18 that mean?  
 19 A. So that the API had the  
 20 right yield, the right specifications,  
 21 environmental conditions were met,  
 22 process went as planned.  
 23 Q. Was it a cGMP requirement  
 24 that the process control would result in

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1 an output of product as you just  
 2 described it?  
 3 A. Was it a cGMP requirement --  
 4 so I was involved in API manufacturing  
 5 for new products.  
 6 What is the GMP requirement?  
 7 Once it's approved, your controls need to  
 8 provide consistent quality, consistent --  
 9 you know, consistently meet  
 10 specifications; so the definition here is  
 11 based on meeting specifications.  
 12 Q. Is that required by GMP, the  
 13 manufacture of a drug product, whether  
 14 API or finished dose, that meets the  
 15 specifications?  
 16 A. So --  
 17 MS. DAVIDSON: Objection.  
 18 Please, Dr. Afnan, 30  
 19 seconds is all I ask.  
 20 THE WITNESS: Okay. Sorry.  
 21 Can you ask the question  
 22 again, please?  
 23 BY MR. SLATER:  
 24 Q. Sure.

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1 You indicated that the  
2 process control was intended to ensure  
3 the output of drug product with  
4 consistent quality, consistently meeting  
5 the specifications.  
6 I'm asking if that was  
7 required by cGMP?  
8 A. The question requires a very  
9 detailed answer; and the very detailed  
10 answer you're going to object to.  
11 Okay. You say that is, it a  
12 GMP requirement? So, effectively, if you  
13 develop a product and you say, for  
14 example, its yield is between 80 percent  
15 to 85 percent, one of the requirements  
16 are that you have a -- develop a trend of  
17 meeting that.  
18 Now, once you develop, you  
19 know, one batch produced at 90 percent  
20 and another batch produced at 70 percent,  
21 that's not a deviation from the GMPs.  
22 You need to look at it. But that's not a  
23 deviation from the GMPs.  
24 That's why I'm struggling

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1 with the question.  
2 Q. One of the things you said  
3 that your process control was supposed to  
4 ensure was consistent quality.  
5 Is the output of API with  
6 consistent quality a requirement of cGMP?  
7 A. So, again, you know,  
8 consistent quality, it depends how -- how  
9 the specs are -- specifications for the  
10 API are determined.  
11 So if the specifications,  
12 which are approved by if regulator, you  
13 know, should you meet those  
14 specifications with every batch? And the  
15 answer is, that's the ideal goal. Will  
16 you meet those every single time? And  
17 the answer is, no, you will not.  
18 So, again, it's not a  
19 black-or-white response that I can give  
20 you.  
21 Q. Does cGMP require that a  
22 manufacturing process yield API that  
23 meets the specifications for that API?  
24 MS. DAVIDSON: Objection.

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1 THE WITNESS: I think I've  
2 answered that. But, again, I'll  
3 try.  
4 cGMPs allow you to fail in  
5 manufacturing a batch. So it's  
6 not a case of, you know, the cGMPs  
7 require that if I make 1,000  
8 batches, they all need to be  
9 identical.  
10 cGMPs do allow batch  
11 failures. If a batch fails, that  
12 means it doesn't meet its  
13 specifications. cGMPs allow that.  
14 BY MR. SLATER:  
15 Q. Would I be correct that cGMP  
16 allows for the possibility of a batch  
17 failure, as you just described it, as  
18 long as you detect and identify the batch  
19 failure?  
20 MS. DAVIDSON: Objection.  
21 THE WITNESS: That's a  
22 circular question. If a batch  
23 fails and it is rejected, then,  
24 obviously, it doesn't reject

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1 itself. It is assessed, analyzed  
2 and, therefore, the quality unit  
3 rejects it.  
4 So if the quality unit  
5 reject it, then -- that's what I  
6 meant by your question is  
7 circular.  
8 BY MR. SLATER:  
9 Q. So if I understand  
10 correctly, cGMP allows a batch failure,  
11 but that's only if the batch failure is  
12 identified by the quality unit and then  
13 that batch failure is identified and that  
14 batch is rejected? Do I understand that  
15 correctly?  
16 MS. DAVIDSON: Objection.  
17 Mischaracterizes his testimony.  
18 THE WITNESS: Yes, it does  
19 mischaracterize my testimony.  
20 That's not what I said.  
21 BY MR. SLATER:  
22 Q. All right. So let me ask  
23 you a different question, then.  
24 Is it your testimony that



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1 cGMP does not require that the API  
2 manufactured with a drug process --  
3 rephrase.  
4 Are you telling me that cGMP  
5 does not require that the API  
6 manufacturing process result in the  
7 output of API that meets the approved  
8 specifications for the drug?  
9 MS. DAVIDSON: Objection.  
10 Again, mischaracterizes testimony.  
11 MR. SLATER: I'm asking the  
12 question.  
13 MS. DAVIDSON: You said, are  
14 you saying, so I thought you were  
15 characterizing his prior  
16 testimony. If not, great.  
17 THE WITNESS: Your approach  
18 to cGMPs is that the cGMPs  
19 determine -- define every activity  
20 of every day. Again, I go back to  
21 very early on when I was saying,  
22 you know, the GMPs define what to  
23 be done and not how to be done.  
24 So the cGMPs do not specify

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1 that, you know what, the batch  
2 needs to be rejected or approved.  
3 The cGMPs create a system, and  
4 that's the uniqueness of the U.S.  
5 regulations, creates a system  
6 within which a manufacturer  
7 manufactures, tests and comes to a  
8 disposition decision.  
9 So cGMPs is a system within  
10 a system. It's like saying, here  
11 is a system for operating within  
12 pharma, and then I have -- I have  
13 a bad batch or I have a semi-bad  
14 batch. Again, not every result  
15 of -- related to specifications of  
16 a batch, you know, can result in a  
17 rejection.  
18 BY MR. SLATER:  
19 Q. What is the purpose of  
20 having specifications for a manufactured  
21 API?  
22 MS. DAVIDSON: Objection.  
23 Vague.  
24 THE WITNESS: If -- I am not

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1 sure I actually understand your  
2 question clearly.  
3 BY MR. SLATER:  
4 Q. Do you want me to explain  
5 it?  
6 A. Please.  
7 Q. If you don't understand it  
8 clearly, then I don't want you to answer  
9 a question you don't understand clearly.  
10 A. Thank you.  
11 Q. Do you know what  
12 specifications for API means? In  
13 general, do you understand what that  
14 means?  
15 MS. DAVIDSON: Objection.  
16 THE WITNESS: You have a  
17 definition for that, right?  
18 BY MR. SLATER:  
19 Q. I'm asking you, you're the  
20 expert. So tell me, what's the  
21 definition of what the specifications for  
22 API is?  
23 What are specifications?  
24 Why do they exist?

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1 A. They are --  
2 MS. DAVIDSON: Objection.  
3 Ali, I don't want to yell at  
4 you. You got to give me time to  
5 object.  
6 THE WITNESS: You know,  
7 specifications are effectively  
8 the -- the bandwidth that we  
9 operate in, okay. That's what the  
10 specification is, it specifies a  
11 parameter and says, this  
12 parameter, plus or minus a  
13 variance, needs to be met or  
14 should be met.  
15 There are specifications and  
16 there are limits. So limits  
17 are -- in the regulated  
18 pharmaceutical world are internal  
19 to the firm. Specifications is  
20 what you agree with the regulator.  
21 BY MR. SLATER:  
22 Q. What is the purpose of  
23 establishing specifications for a  
24 manufactured API?



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1 A. What's the purpose of  
2 specifications for a manufactured API?  
3 It's so that when we talk about that API,  
4 we are talking about the same product,  
5 regardless of who the manufacturer is.  
6 However, there are  
7 differences between those manufactured  
8 products by different manufacturers.  
9 MS. DAVIDSON: We've been  
10 going about an hour. Is this a  
11 good time for a break?  
12 MR. SLATER: I'm actually  
13 ready to keep going for as long as  
14 we possibly can. I don't need a  
15 break.  
16 MS. DAVIDSON: Dr. Afnan, do  
17 you need a break?  
18 THE WITNESS: I would  
19 appreciate a break.  
20 MS. DAVIDSON: Okay. Let's  
21 take ten minutes.  
22 VIDEO TECHNICIAN: We're off  
23 the record at 10:37 a.m.  
24 - - -

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1 (Whereupon, a brief recess  
2 was taken.)  
3 - - -  
4 VIDEO TECHNICIAN: We're  
5 back on the record at 10:47 a.m.  
6 BY MR. SLATER:  
7 Q. You said the purpose of  
8 specifications for an API is so that when  
9 we talk about the API it's the same  
10 product, regardless of manufacturer,  
11 correct?  
12 MS. DAVIDSON: Objection.  
13 THE WITNESS: Okay. "Same"  
14 is an interesting word to use.  
15 And if I used same, it was -- it  
16 has to be qualified.  
17 So, effectively, when we  
18 look at USP monographs, it defines  
19 specifications for an API. And  
20 that has a range for purity,  
21 impurity, unknown impurity, so on  
22 and so forth.  
23 BY MR. SLATER:  
24 Q. When you say there's "a

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1 range," what do you mean?  
2 A. So, for example, it will say  
3 98 percent to 102 percent purity. It  
4 says, you know, impurities or a specific  
5 impurity below a certain limit. It  
6 states unknown impurities below .1  
7 percent or 1 percent or .5 percent. It  
8 varies from product to product.  
9 Q. If there are unknown  
10 impurities -- well, rephrase.  
11 Are all -- rephrase.  
12 Are all unknown impurities  
13 evaluated in the same way in terms of  
14 whether or not it's acceptable for them  
15 to exist in an API?  
16 MS. DAVIDSON: Objection.  
17 THE WITNESS: If it's an  
18 unknown impurity, how would one  
19 assess it to see if it's supposed  
20 to be there or not? So could you  
21 please rephrase your question?  
22 BY MR. SLATER:  
23 Q. No. Actually, I think I'll  
24 ask a follow-up question.

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1 Unknown impurities need to  
2 be assessed in order to identify what  
3 they are because all impurities are not  
4 treated the same, in terms of how much  
5 can exist in an API or drug product,  
6 correct?  
7 MS. DAVIDSON: Objection.  
8 THE WITNESS: ICH Q3A  
9 specifically defines and allows  
10 for unknown impurities to remain  
11 in a product. And an unknown  
12 impurity is that, it's not known;  
13 we don't know what it does.  
14 You -- you know, all that is there  
15 is what level and what the limit  
16 is for it.  
17 BY MR. SLATER:  
18 Q. If an unknown impurity is  
19 below whatever threshold you are applying  
20 as a manufacturer and the amount of that  
21 impurity under that threshold is  
22 sufficient to kill every single person  
23 who takes the drug product, is that  
24 acceptable?

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1 MS. DAVIDSON: Objection.  
 2 THE WITNESS: If it's an  
 3 unknown impurity, how would a  
 4 manufacturer know of the effect of  
 5 an unknown impurity?  
 6 BY MR. SLATER:  
 7 Q. In forming your opinions in  
 8 this case, is it your foundational  
 9 assumption that it's impossible for an  
 10 API manufacturer to identify the unknown  
 11 impurities created by a manufacturing  
 12 process?  
 13 MS. DAVIDSON: Objection.  
 14 BY MR. SLATER:  
 15 Q. Let me ask the question  
 16 differently.  
 17 A. Okay.  
 18 Q. Is it your testimony that it  
 19 is impossible for an API manufacturer,  
 20 like ZHP, to identify the source of  
 21 impurities that are below the applicable  
 22 threshold but are not known?  
 23 Are you saying it's  
 24 impossible to figure out what they

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1 actually are?  
 2 MS. DAVIDSON: Objection.  
 3 THE WITNESS: I didn't say  
 4 it's impossible. We need to go  
 5 back to ICH and see what ICH says,  
 6 even though it's a guidance and it  
 7 allows for unknown impurities  
 8 below a certain limit to be  
 9 present.  
 10 There is no requirement to  
 11 go and identify every single  
 12 unknown impurity and see  
 13 whether -- you know, what the  
 14 function of that impurity is.  
 15 BY MR. SLATER:  
 16 Q. So that comes back to my  
 17 prior question.  
 18 If there's no requirement to  
 19 identify all unknown impurities, would it  
 20 be acceptable, under cGMP, if there was  
 21 an unknown impurity below the ICH Q3A  
 22 threshold that, if ingested by a human  
 23 being, would kill the person within one  
 24 day?

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1 A. Wow.  
 2 MS. DAVIDSON: I don't know  
 3 if that "wow" covers my objection.  
 4 You didn't give me a chance.  
 5 But I was intending to  
 6 object.  
 7 THE WITNESS: Well, that was  
 8 an objection from me.  
 9 MS. DAVIDSON: I don't think  
 10 you're allowed to do that,  
 11 Dr. Afnan.  
 12 THE WITNESS: Sorry.  
 13 MS. DAVIDSON: That's my  
 14 job.  
 15 THE WITNESS: Can you repeat  
 16 your question, please? Or I would  
 17 really prefer you to rephrase the  
 18 question.  
 19 MR. SLATER: Please read the  
 20 question back to him, please.  
 21 - - -  
 22 (Whereupon, the court  
 23 reporter read the following part  
 24 of the record:

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1 "Question: So that comes  
 2 back to my prior question.  
 3 "If there's no requirement  
 4 to identify all unknown  
 5 impurities, would it be  
 6 acceptable, under cGMP, if there  
 7 was an unknown impurity below the  
 8 ICH Q3A threshold that, if  
 9 ingested by a human being, would  
 10 kill the person within one day?"  
 11 - - -  
 12 MS. DAVIDSON: Objection.  
 13 THE WITNESS: I don't even  
 14 know how to begin to answer that  
 15 question, because it is such a  
 16 far-fetched question that -- you  
 17 know, if it was below the  
 18 threshold limit?  
 19 If it's below the threshold  
 20 limit, the pharma manufacturer  
 21 doesn't know about it, because  
 22 it's unknown.  
 23 So the GMPs allow -- or,  
 24 more specifically, the

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1 specifications allow to have  
2 unknown impurities.  
3 Now, if it's a generic API,  
4 then it's following the branded  
5 API. If it's a brand API, then it  
6 will have gone through multiple  
7 different clinical studies where  
8 the intent would have been to  
9 identify a poisonous compound.  
10 BY MR. SLATER:  
11 Q. Are all potential impurities  
12 subject to the same threshold?  
13 A. So the threshold depends on  
14 your analytical methodology. It's not  
15 just the case of, you know, here I draw a  
16 line and I call it a threshold and then  
17 move on.  
18 So I think your -- your  
19 question needs exploring, it needs to be  
20 changed.  
21 Q. Did you ever hear of the  
22 cohort of concern?  
23 A. Yes.  
24 Q. When did you first hear of

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1 the cohort of concern?  
2 A. The cohorts of concern are  
3 in M7, that's where I heard.  
4 Q. When? When did you first  
5 learn of the cohort of concern?  
6 MS. DAVIDSON: Objection.  
7 THE WITNESS: As I have said  
8 earlier, when I was working on --  
9 when I was working on drug  
10 development with -- outside of  
11 this project, this case, I had  
12 read M7.  
13 So that goes back, you know,  
14 before I started with this  
15 project.  
16 BY MR. SLATER:  
17 Q. What is the cohort of  
18 concern?  
19 A. So M7 defines -- or lists  
20 cohorts of concern, which effectively  
21 lists a different set of types of  
22 products or compounds and says, these are  
23 of concern.  
24 There is a, you know --

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1 Q. What is the cohort of  
2 concern? What substances comprise the  
3 cohort of concern?  
4 MS. DAVIDSON: Objection.  
5 BY MR. SLATER:  
6 Q. Do you know?  
7 A. I would appreciate if you  
8 could show me M7, and I will direct you  
9 to it.  
10 Q. I don't have M7 at my  
11 fingertips.  
12 A. I don't have the list  
13 learned by heart either.  
14 Q. N-nitroso compounds are part  
15 of the cohort of concern, correct?  
16 MS. DAVIDSON: Objection.  
17 THE WITNESS: Again, this is  
18 not something I have learned by  
19 heart. I would really appreciate  
20 if we could look at M7.  
21 BY MR. SLATER:  
22 Q. You don't know, as you sit  
23 here right now without looking at M7,  
24 whether N-nitroso compounds are part of

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1 the cohort of concern?  
2 MS. DAVIDSON: Objection.  
3 Badgering the witness.  
4 THE WITNESS: I am --  
5 MS. DAVIDSON: Please don't  
6 interrupt me, Dr. Afnan.  
7 If you would like to pull up  
8 M7, that is permissible in this  
9 deposition, as Adam told his own  
10 witnesses.  
11 THE WITNESS: Okay.  
12 BY MR. SLATER:  
13 Q. Is the answer you can't  
14 answer the question without seeing M7?  
15 MS. DAVIDSON: Objection.  
16 Mischaracterizes his testimony.  
17 Badgering the witness.  
18 BY MR. SLATER:  
19 Q. I need to know, Doctor.  
20 Are you telling me that  
21 without looking at M7 you can't tell me  
22 if N-nitroso compounds are part of the  
23 cohort of concern?  
24 MS. DAVIDSON: Same

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1 objections.

2 THE WITNESS: So my response

3 is delayed or not given to you.

4 The reason I'm asking for M7

5 is because you're using a very

6 specific phrase, "N-nitroso

7 compounds." I would like to see

8 if M7 says N-nitroso compounds.

9 BY MR. SLATER:

10 Q. Do you -- do you know what

11 NDMA is?

12 A. Yes.

13 Q. What is NDMA?

14 A. Nitrosodimethylamine.

15 Q. Do you know -- do you know

16 what NDEA is?

17 MS. DAVIDSON: I'm sorry.

18 Objection. When you say what it

19 is, are you asking him what the

20 abbreviation stands for or what it

21 is? I think the question is

22 vague.

23 BY MR. SLATER:

24 Q. Do you know what NDEA is?

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1 MS. DAVIDSON: So I'm going

2 to have to have the same objection

3 if you don't want to clarify the

4 question.

5 THE WITNESS: It stands for

6 nitrosodiethylamine.

7 BY MR. SLATER:

8 Q. Are NDMA and NDEA N-nitroso

9 compounds?

10 A. Yes.

11 Q. Does the threshold approach

12 to impurities apply to NDMA and NDEA?

13 MS. DAVIDSON: Objection.

14 Are you asking -- can you repeat

15 the question, madam court

16 reporter?

17 BY MR. SLATER:

18 Q. Sure.

19 Does the threshold approach

20 to impurities apply to NDMA and NDEA?

21 MS. DAVIDSON: So you're

22 asking currently? Is that a

23 present-tense question?

24 Q. During the time --

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1 MS. DAVIDSON: Otherwise I'm

2 going to object as vague.

3 MR. SLATER: Okay.

4 BY MR. SLATER:

5 Q. During the time that ZHP

6 developed and manufactured valsartan API,

7 did the threshold approach to impurities

8 apply to NDMA and NDEA?

9 A. Your question is based on

10 today, looking back at 2000 -- you know,

11 prior to 2018.

12 So to actually look at

13 cohorts of concern, M7, I think, based on

14 my recollection, is that an assessment

15 needs to be done of the process to see

16 whether nitroso compounds would be

17 formed. And if there is no -- if the

18 conclusion is that no mutagenic compounds

19 are formed, then the unknown impurities

20 will remain unknown.

21 ICH Q3A is also on the side

22 of -- you know, parallel to M7, not on

23 the side, parallel to M7. And ICH Q3A,

24 at that time, and even today, says

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1 certain impurities can be below the

2 threshold limit, and below .1 percent you

3 can have unknown -- undefined,

4 uncharacterized impurities.

5 Q. One of the things ZHP was

6 required to do was to assess its

7 manufacturing process for valsartan API,

8 correct?

9 A. It was, yes. And it did.

10 Q. Why did you add the part

11 about "and it did"?

12 A. Because -- because it did.

13 Q. But did I ask you if they

14 did or not?

15 A. No.

16 MS. DAVIDSON: Objection. I

17 don't know if that's actually a

18 question you're asking in a

19 deposition. That's -- you're

20 obviously badgering the witness.

21 MR. SLATER: I don't think I

22 am. What I'm doing is trying

23 to -- I'm trying to determine the

24 witness's understanding of my

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<p>1 questions. And I'm trying to 2 understand why it is he said they 3 did, when I didn't ask the 4 question. 5 So I'm trying to understand 6 why he said it when I didn't ask 7 the question about whether they 8 did it or not. 9 MS. DAVIDSON: Okay. I 10 don't think you're really trying 11 to understand that. This is 12 Dr. Afnan's first deposition, as 13 he indicated at the beginning of 14 the deposition. 15 So I think let's just give 16 the man a break and move on with 17 actual questioning. 18 MR. SLATER: Right. We're 19 here to give ZHP and their expert 20 witness on GMP a break today. 21 MS. DAVIDSON: I don't know 22 what that means. 23 BY MR. SLATER: 24 Q. ZHP was required to</p>	<p>1 back to me, please? 2 Q. I'll ask it again. I'll try 3 to be even clearer. 4 A. Sure. 5 Q. In terms of assessing the 6 risks of introduction of a chemical or a 7 substance to the manufacturing process, 8 one of the risks that needed to be 9 assessed was whether that chemical or 10 substance would introduce impurities into 11 the process, correct? 12 A. Yes. 13 Q. And that assessment is 14 expected to be or required by cGMP to be 15 a scientific assessment, correct? 16 A. Can you tell me what you 17 mean by "scientific"? 18 Q. The assessment needs -- 19 rephrase. 20 The assessment needed to be 21 based on scientific information that was 22 available to those people who were in 23 charge of this process, for example, 24 information that was available in the</p>
Page 91	Page 93
<p>1 assess -- rephrase. 2 When ZHP changed the 3 manufacturing process for valsartan, did 4 they need to understand the properties of 5 the chemicals and substances that they 6 were introducing to the process? 7 MS. DAVIDSON: Objection. 8 Vague. 9 THE WITNESS: Can you please 10 let me know what you mean by 11 "properties" of substances? 12 BY MR. SLATER: 13 Q. Their function, their 14 benefits to the process, potentially, and 15 their potential risks as being introduced 16 into the process as well. 17 Did they need to assess 18 those things? 19 A. Yes. 20 Q. One of the things that that 21 assessment needed to involve was the 22 potential risk of introduction of 23 impurities into the product, correct? 24 A. Can you read that question</p>	<p>1 scientific literature, correct? 2 A. So the way they would be 3 expected and the way which is current 4 practice, and was practice at that time, 5 was for the firm to look at the process, 6 to look at the raw materials that it was 7 buying, making sure that those materials 8 met specifications; and then look at the 9 process and assess whether an undesired 10 side reaction will take place. 11 If those did not take place, 12 then there would not be a logical reason 13 for -- a scientific reason for going and 14 trolling through the scientific community 15 to see what else would happen. 16 So it is a -- it isn't a 17 black-and-white, you know what, they 18 should have -- they should have looked at 19 everything in the scientific community, 20 because that's not logical. 21 Q. Before ZHP introduced a new 22 substance into the manufacturing process, 23 it needed to understand -- well, let me 24 walk back, actually.</p>



<p style="text-align: right;">Page 94</p> <p>1 One of the things you said                  2 is that they must look at the raw                  3 materials it was buying and make sure                  4 they meet the specifications; is that one                  5 of the things you said?                  6 A. They -- industry generally                  7 requires to qualify its vendors.                  8 Q. What does it mean to qualify                  9 a vendor?                  10 A. To look at a vendor, to make                  11 sure that the vendor has acceptable GMPs,                  12 and the substance which is coming in,                  13 there are specifications, and those                  14 specifications can be met.                  15 Q. In terms of understanding                  16 the specifications for the substances                  17 that are being purchased from vendors,                  18 that would include, for example, if a                  19 solvent was being purchased for use in a                  20 manufacturing process, correct?                  21 A. Sorry, can you repeat the                  22 question?                  23 Q. Sure.                  24 When you talk about looking</p>	<p style="text-align: right;">Page 96</p> <p>1 API product, are you?                  2 MS. DAVIDSON: Objection.                  3 BY MR. SLATER:                  4 Q. Is that what you mean, that                  5 staying in the process means it ends                  6 up -- that that solvent is a part of the                  7 finished API that comes out of the                  8 process?                  9 MR. SLATER: I just want to                  10 understand what the doctor is                  11 saying.                  12 MS. DAVIDSON: Objection.                  13 You asked a question and I                  14 objected. And then you asked a                  15 new question, and now I don't know                  16 which of the two questions is                  17 pending.                  18 If you changed your first                  19 question to the second question, I                  20 object to the second question.                  21 BY MR. SLATER:                  22 Q. When you refer to the                  23 process -- rephrase.                  24 When you refer to the</p>
<p style="text-align: right;">Page 95</p> <p>1 at the specifications for the substances                  2 that are being purchased from vendors,                  3 that would include, for example, if the                  4 manufacturer purchased a solvent to be                  5 used in the manufacturing process,                  6 correct?                  7 A. So there is a qualification                  8 to my response, which is defined in                  9 ICH Q7. ICH Q7 categorizes intermediates                  10 and raw materials which are purchased for                  11 use in an API process.                  12 And that effectively depends                  13 whether that solvent is expected to                  14 remain in the process or whether it will                  15 be removed from the process during                  16 processing.                  17 So as you get closer to that                  18 solvent remaining in the process, they --                  19 the regulatory requirement or the GMP                  20 requirement goes up.                  21 Q. When you say if that solvent                  22 remains in the process, you're not saying                  23 it has to remain so long that it ends up                  24 in the finished drug -- in the finished</p>	<p style="text-align: right;">Page 97</p> <p>1 substance, in this case we're talking                  2 about a solvent, remaining in the                  3 process, are you saying remaining in the                  4 process until the end so that the solvent                  5 is actually in the API product that is                  6 yielded by the process?                  7 MS. DAVIDSON: Objection.                  8 THE WITNESS: So the way the                  9 regulations work, the way the GMPs                  10 work, if you get a solvent which                  11 is used in your processing, the                  12 question that comes up that needs                  13 to be taken into consideration by                  14 the firm is whether the downstream                  15 processing steps would effectively                  16 remove that solvent from the                  17 process.                  18 However, in industrial                  19 setting productions, it is                  20 extremely rare for all the                  21 solvents to be removed from the                  22 process. And for that reason,                  23 most of the solvents which are                  24 used in industry all have an</p>



<p style="text-align: right;">Page 98</p> <p>1 allowable limit in the API, in the</p> <p>2 finished API.</p> <p>3 BY MR. SLATER:</p> <p>4 Q. Does ICH Q7 require that</p> <p>5 when ZHP purchased, for example, DMF from</p> <p>6 a supplier, that it would either test the</p> <p>7 DMF to see what it contained or rely on</p> <p>8 the supplier's certificate of analysis</p> <p>9 for that DMF to know what the DMF</p> <p>10 contained?</p> <p>11 MS. DAVIDSON: Objection.</p> <p>12 THE WITNESS: So Q7 doesn't</p> <p>13 address ZHP at all. Q7 addresses</p> <p>14 the what-to-do of pharma for APIs.</p> <p>15 Again, if I look at Q7, Q7</p> <p>16 would require the quality unit --</p> <p>17 a part of Q7 would require that</p> <p>18 the solvent supplier be qualified,</p> <p>19 that the solvent supplier sell,</p> <p>20 your example of DMF,</p> <p>21 dimethylformamide, and that</p> <p>22 dimethylformamide would have a</p> <p>23 specification which is provided by</p> <p>24 the firm. And the C of A is</p>	<p style="text-align: right;">Page 100</p> <p>1 zinc chloride process?</p> <p>2 MS. DAVIDSON: Objection.</p> <p>3 THE WITNESS: According to</p> <p>4 FDA inspections of ZHP and, in</p> <p>5 particular, the 2018 for-cause</p> <p>6 inspection where the inspector</p> <p>7 says there is a quality unit which</p> <p>8 is well established, I would</p> <p>9 conclude, based on that, that ZHP</p> <p>10 would have been testing materials</p> <p>11 coming in and would have had met</p> <p>12 the regulatory requirements.</p> <p>13 Because during the for-cause</p> <p>14 inspection, the investigator says</p> <p>15 their quality and it is</p> <p>16 established it is operating well.</p> <p>17 Previous inspections also found</p> <p>18 that the quality unit was</p> <p>19 functioning properly.</p> <p>20 BY MR. SLATER:</p> <p>21 Q. So that I understand -- let</p> <p>22 me just take a step back.</p> <p>23 The reason I'm asking some</p> <p>24 of these questions, so you know where I'm</p>
<p style="text-align: right;">Page 99</p> <p>1 provided with every batch.</p> <p>2 According to current practice, or</p> <p>3 good manufacturing practice, the</p> <p>4 customer -- you know, a customer,</p> <p>5 a manufacturer, an API</p> <p>6 manufacturer, would qualify that</p> <p>7 solvent, number one, and then it</p> <p>8 would do IE testing of the batches</p> <p>9 throughout the year. And at least</p> <p>10 one batch would be fully tested,</p> <p>11 as per the C of A. So if there</p> <p>12 are five tests on the C of A,</p> <p>13 those five tests would be run by</p> <p>14 the API manufacturers.</p> <p>15 BY MR. SLATER:</p> <p>16 Q. When you say they test per</p> <p>17 the C of A, is that to compare what their</p> <p>18 tests show versus what the certificate of</p> <p>19 analysis shows should be within the</p> <p>20 substance?</p> <p>21 A. Yes.</p> <p>22 Q. Do you know whether ZHP ever</p> <p>23 looked at the certificate of analysis for</p> <p>24 the DMF that it purchased and used in the</p>	<p style="text-align: right;">Page 101</p> <p>1 going is, you're coming in as an expert</p> <p>2 to try to give opinions. You didn't live</p> <p>3 through this, so you have to have your</p> <p>4 own understanding of the facts, based on</p> <p>5 the materials provided to you.</p> <p>6 You looked at a lot of</p> <p>7 documents, you looked at testimony, you</p> <p>8 looked at various things in order to</p> <p>9 understand what you think the facts are,</p> <p>10 right?</p> <p>11 MS. DAVIDSON: Objection. I</p> <p>12 don't know if that was actually a</p> <p>13 question or --</p> <p>14 MR. SLATER: I'll ask</p> <p>15 another question, because I don't</p> <p>16 want to dismay you.</p> <p>17 BY MR. SLATER:</p> <p>18 Q. Doctor, did you draw certain</p> <p>19 factual assumptions in order to then form</p> <p>20 opinions?</p> <p>21 MS. DAVIDSON: Objection.</p> <p>22 THE WITNESS: Can you</p> <p>23 rephrase or repeat the question?</p> <p>24 BY MR. SLATER:</p>

<p style="text-align: right;">Page 102</p> <p>1 Q. Sure.</p> <p>2 In order to form the</p> <p>3 opinions you formed in this case, did you</p> <p>4 rely on certain factual assumptions so</p> <p>5 that you said to yourself, okay, the</p> <p>6 facts are this, so based on these facts,</p> <p>7 my opinion is this?</p> <p>8 MS. DAVIDSON: Objection.</p> <p>9 BY MR. SLATER:</p> <p>10 Q. Did you do that as part of</p> <p>11 your methodology here?</p> <p>12 MS. DAVIDSON: Objection. I</p> <p>13 think when you ask one question,</p> <p>14 let's stop at that question, have</p> <p>15 the objection, have an answer.</p> <p>16 Because we have this pattern</p> <p>17 where I object and then you have,</p> <p>18 like, a follow-up question. I</p> <p>19 think it's creating a very unclear</p> <p>20 record.</p> <p>21 THE WITNESS: So the scope</p> <p>22 of my work was to assess whether</p> <p>23 they followed the GMPs</p> <p>24 specifically in relation to the</p>	<p style="text-align: right;">Page 104</p> <p>1 for the DMF it purchased for use in the</p> <p>2 zinc chloride process; do I understand</p> <p>3 you correctly?</p> <p>4 A. So, first of all, it's a</p> <p>5 solvent that is added to the process and</p> <p>6 then removed from the process, based on</p> <p>7 the process description that ZHP gives.</p> <p>8 That makes it a low-risk,</p> <p>9 low-category ingredient going into the</p> <p>10 process, number one.</p> <p>11 Number two, did I draw any</p> <p>12 conclusions that they must have looked at</p> <p>13 the C of A? And the answer is, if they</p> <p>14 did not, if they had not released their</p> <p>15 DMF, their solvents, they would have been</p> <p>16 cited over and over and over.</p> <p>17 Q. Is it your understanding, in</p> <p>18 forming your opinions, that ZHP looked at</p> <p>19 the certificates of analysis for the DMF</p> <p>20 it purchased for use in the zinc chloride</p> <p>21 process; yes or no?</p> <p>22 MS. DAVIDSON: Objection.</p> <p>23 THE WITNESS: ZHP looked at</p> <p>24 the C of As of the DMF it</p>
<p style="text-align: right;">Page 103</p> <p>1 issues here and specifically in</p> <p>2 relation to plaintiffs' expert</p> <p>3 reports, which have been</p> <p>4 submitted.</p> <p>5 None of the expert</p> <p>6 reports -- the plaintiffs' expert</p> <p>7 reports, question the C of A or</p> <p>8 the solvent purchased by DMF.</p> <p>9 So did I have certain</p> <p>10 assumptions? My point is, I am a</p> <p>11 GMP assessor in this case, and I'm</p> <p>12 looking to see whether ZHP adhered</p> <p>13 to the GMPs or not.</p> <p>14 And in the same way an</p> <p>15 inspector would go on site and</p> <p>16 make conclusions and draw</p> <p>17 conclusions, I am relying on what</p> <p>18 I call facts that the inspector</p> <p>19 writes in her EIR and in her</p> <p>20 observations.</p> <p>21 BY MR. SLATER:</p> <p>22 Q. So one of the assumptions</p> <p>23 that you drew in this case is that ZHP</p> <p>24 looked at the certificates of analysis</p>	<p style="text-align: right;">Page 105</p> <p>1 purchased.</p> <p>2 BY MR. SLATER:</p> <p>3 Q. Did you ever look at any</p> <p>4 certificate of analysis in connection</p> <p>5 with the DMF that was purchased by ZHP</p> <p>6 and used in the zinc chloride process?</p> <p>7 I just want to know if you</p> <p>8 ever saw any certificate of analysis for</p> <p>9 that DMF.</p> <p>10 COURT REPORTER: Ms.</p> <p>11 Davidson, you're on mute.</p> <p>12 MS. DAVIDSON: Sorry about</p> <p>13 that. I was objecting.</p> <p>14 I'm glad you can read lips.</p> <p>15 THE WITNESS: So ZHP, in its</p> <p>16 investigation that it sent to FDA,</p> <p>17 lists the DMF suppliers and the</p> <p>18 quality of those DMF supplies.</p> <p>19 Now, did I look at the</p> <p>20 specific C of A? I honestly do</p> <p>21 not recall.</p> <p>22 BY MR. SLATER:</p> <p>23 Q. That's all I asked you.</p> <p>24 I just asked you if you saw</p>

1 any certificate of analysis for the DMF.  
2 MS. DAVIDSON: Objection. I  
3 don't know if that's a question  
4 or --

5 BY MR. SLATER:

6 Q. So the point is, you don't  
7 recall, correct?

8 MS. DAVIDSON: Objection.  
9 Asked and answered.

10 THE WITNESS: I looked at  
11 the data that was presented to  
12 FDA, which FDA accepted. That, I  
13 do remember.

14 I do not remember  
15 specifically looking at the C of A  
16 of DMF.

17 MR. SLATER: We're going to  
18 put up an exhibit. For purposes  
19 of this deposition, I think this  
20 is Exhibit 5 or 6. This is  
21 Exhibit-5.

22 - - -

23 (Whereupon, Exhibit Afnan-5,  
24 PRINSTON00075810-6099, Deviation

1 Investigation Report, was marked  
2 for identification.)  
3 - - -

4 BY MR. SLATER:

5 Q. So to be clear, Exhibit-5 on  
6 the screen is the deviation investigation  
7 report, which was actually marked at a  
8 prior deposition Peng Dong as ZHP 210.

9 Do you see that document on  
10 the screen?

11 A. I see it. I would  
12 appreciate it if it could also be put  
13 into the share folder.

14 Q. It's there.

15 A. Okay. Thank you.

16 Q. Have you seen this document  
17 before?

18 A. That is the investigation I  
19 was referring to.

20 Q. Was this a document that was  
21 significant to you in evaluating this  
22 case and forming your opinions?

23 MS. DAVIDSON: Objection.

24 THE WITNESS: This was one

1 of the documents that was of  
2 significance to me.

3 BY MR. SLATER:

4 Q. Let's go to Page 7 of 236 of  
5 this document, please. I'm looking at  
6 the bottom part of the page.

7 This states, Based on the  
8 investigation and the evaluation of the  
9 current valsartan route of  
10 synthesis (zinc chloride process), this  
11 impurity is most likely formed during the  
12 azide quenching by nitric acid of the API  
13 manufacturing process.

14 Do you see where I'm reading  
15 under Figure 3.1, which says, The  
16 structure of NDMA? Do you see where I'm  
17 reading?

18 A. Yes.

19 Q. Continuing, it says,  
20 Specifically, dimethylformamide (DMF) one  
21 of the solvents used in Step 4 (Crude)  
22 stage, may contain trace amount of  
23 dimethylamine as an impurity.  
24 Furthermore, during the tetrazole

1 formation step, dimethylformamide may be  
2 susceptible to low-level decomposition  
3 under high temperature to produce trace  
4 amount of dimethylamine, either by thermo  
5 decomposition or hydrolysis.

6 Do you see where I just  
7 read?

8 A. Yes.

9 Q. Did you read that language  
10 as part of your evaluation of this case  
11 in forming your opinions?

12 A. Yes.

13 Q. So when you formed your  
14 opinions in this case, you were aware  
15 that dimethylamine could be introduced --  
16 rephrase.

17 So when you formed your  
18 opinions in this case, you understood  
19 that ZHP had determined that the DMF that  
20 it was using in the zinc chloride process  
21 may contain a trace amount of  
22 dimethylamine as an impurity before it  
23 even was added to the process; you had  
24 read that language and understood it when

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1 you formed your opinions, correct?  
2 MS. DAVIDSON: Objection.  
3 THE WITNESS: So what is  
4 interesting is, what is the date  
5 of this document? Can you go to  
6 the top or the bottom, or  
7 wherever, and tell me what's the  
8 date of that document?  
9 MS. DAVIDSON: I believe,  
10 Dr. Afnan, if it was placed in  
11 the --  
12 MR. SLATER: It's November  
13 5, 2018.  
14 BY MR. SLATER:  
15 Q. Please answer the question.  
16 MS. DAVIDSON: Adam, you  
17 interrupted me.  
18 Dr. Afnan, I believe if a  
19 document has been placed in the  
20 share drive, or whatever it's  
21 called, as Adam noted, that you  
22 can move up and down on it  
23 yourself.  
24 You can open it; is that

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1 correct?  
2 THE WITNESS: Yes.  
3 MS. DAVIDSON: I just wanted  
4 to clarify that.  
5 THE WITNESS: Thank you.  
6 So this was an investigation  
7 taking place -- in fact, this was  
8 Version Number 2, as it says on  
9 the screen.  
10 This was an investigation  
11 which was taking place where ZHP  
12 was trying to find the root cause  
13 and the method of formation of  
14 NDMA in the process.  
15 This is not a statement  
16 about, you know what, this is what  
17 we did. They are testing every  
18 single possible pathway to  
19 formation of NDMA. This document  
20 is being written with a 20/20  
21 hindsight that NDMA was present in  
22 valsartan. And as requested and  
23 required by their system and FDA,  
24 they're digging into where is this

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1 NDMA coming from.  
2 BY MR. SLATER:  
3 Q. My question was simply  
4 whether you took that information that I  
5 just read with you into consideration  
6 when you formed your opinions.  
7 It's a yes-or-no question.  
8 I just want to know if you took it into  
9 account when you formed your opinions.  
10 MS. DAVIDSON: Objection.  
11 Again, I'm going to have to object  
12 every time you say it's a  
13 yes-or-no question.  
14 THE WITNESS: I actually do  
15 not believe I can give you a  
16 yes-or-no answer.  
17 So if -- again, you know,  
18 FDA said -- Dr. Gottlieb, on the  
19 30th of August, 2018, says,  
20 because it was not anticipated  
21 that NDMA would occur at these  
22 levels in the manufacture of the  
23 valsartan API, manufacturers would  
24 not have been testing for it.

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1 That's what FDA said.  
2 BY MR. SLATER:  
3 Q. Can you just answer my  
4 question, please?  
5 A. I did. I can't give you a  
6 yes-or-no answer.  
7 Would you like to rephrase  
8 your question?  
9 Q. You told me a moment ago  
10 that you read this language when you were  
11 preparing your report, correct?  
12 A. Yes.  
13 Q. So you knew this information  
14 when you wrote your report, correct?  
15 MS. DAVIDSON: Objection.  
16 THE WITNESS: I had to take  
17 everything that I read in the  
18 context of why, when, how, and why  
19 am I reading it.  
20 Again, this is a 20/20  
21 hindsight in 2018, back end of  
22 2018, where ZHP is making --  
23 effectively trying to make NDMA.  
24 And this is the report of them



<p style="text-align: right;">Page 114</p> <p>1 trying, trying, to make NDMA. So</p> <p>2 they write this report when they</p> <p>3 are trying to make NDMA.</p> <p>4 So did I read this when I --</p> <p>5 before writing my report? Yes,</p> <p>6 the answer is, I read this before</p> <p>7 I wrote my report.</p> <p>8 BY MR. SLATER:</p> <p>9 Q. Having read this, did you</p> <p>10 consider the possibility that</p> <p>11 dimethylamine was introduced to the zinc</p> <p>12 chloride process as an impurity of DMF?</p> <p>13 Did you consider that as one</p> <p>14 of the pathways by which the NDMA got</p> <p>15 into the process; yes or no?</p> <p>16 MS. DAVIDSON: Objection. I</p> <p>17 think that's --</p> <p>18 THE WITNESS: Again, the</p> <p>19 scope of my work was to look at</p> <p>20 the plaintiff experts reports and</p> <p>21 assess that, as well as the GMP</p> <p>22 assessment. My scope was not to</p> <p>23 dig into the chemistry of the</p> <p>24 formation of NDMA.</p>	<p style="text-align: right;">Page 116</p> <p>1 to me -- indicated, to me, that DMF,</p> <p>2 which is a very common solvent, actually,</p> <p>3 in the pharma industry, that if it's used</p> <p>4 it would have followed certain -- certain</p> <p>5 common practices, certain behaviors, you</p> <p>6 know, certain practices that were</p> <p>7 practiced across industry.</p> <p>8 And, again, your question of</p> <p>9 could this have come with DMF, the answer</p> <p>10 goes back to, this text that you're</p> <p>11 showing me is -- is a hypothesis of this</p> <p>12 could have come -- it's a hypothesis that</p> <p>13 this could have come.</p> <p>14 As it says, it's most</p> <p>15 likely formed during the azide quenching</p> <p>16 by nitrous acid of the API. One of the</p> <p>17 solvents used and inspected for may</p> <p>18 contain trace amounts of dimethylamine as</p> <p>19 an impurity.</p> <p>20 Q. You just said that because</p> <p>21 DMF was a very common solvent you would</p> <p>22 expect that there would be certain</p> <p>23 familiarity with DMF within the industry</p> <p>24 and that certain common practices would</p>
<p style="text-align: right;">Page 115</p> <p>1 And, again, I'll repeat,</p> <p>2 this report is a look-back after</p> <p>3 ZHP knew NDMA had been formed, and</p> <p>4 they were now looking at the</p> <p>5 pathways of formation of NDMA.</p> <p>6 This is after -- this</p> <p>7 report, this language, is after</p> <p>8 the language by Scott Gottlieb,</p> <p>9 FDA commissioner, which said it</p> <p>10 was not anticipated that NDMA</p> <p>11 would occur at these levels in the</p> <p>12 manufacture of the valsartan APIs</p> <p>13 and manufacturers were not testing</p> <p>14 for it.</p> <p>15 BY MR. SLATER:</p> <p>16 Q. In forming your opinions,</p> <p>17 did you consider the possibility that the</p> <p>18 dimethylamine was introduced to the zinc</p> <p>19 chloride process as an impurity of DMF as</p> <p>20 the DMF was purchased?</p> <p>21 A. So there is no monograph for</p> <p>22 DMF that I have been able to find. There</p> <p>23 are specifications for levels of DMF in</p> <p>24 finished APIs which effectively indicate,</p>	<p style="text-align: right;">Page 117</p> <p>1 be followed.</p> <p>2 Can you tell me, first of</p> <p>3 all -- well, let me rephrase the</p> <p>4 question.</p> <p>5 Do you have an opinion as to</p> <p>6 what, as a matter of GMP, the people at</p> <p>7 ZHP should have understood about the</p> <p>8 potential impurities within DMF when they</p> <p>9 decided to use that solvent in the zinc</p> <p>10 chloride process?</p> <p>11 MS. DAVIDSON: Objection.</p> <p>12 THE WITNESS: Can you either</p> <p>13 repeat or rephrase, please?</p> <p>14 BY MR. SLATER:</p> <p>15 Q. Sure. I'll rephrase it.</p> <p>16 I'm actually going to ask it differently.</p> <p>17 When you referred a moment</p> <p>18 ago to certain practices in the industry,</p> <p>19 what specific practices, with regard to</p> <p>20 DMF, are you aware of that you would</p> <p>21 expect ZHP followed?</p> <p>22 A. So industry --</p> <p>23 Q. I'm not asking -- by the</p> <p>24 way, just to be clear, I'm not asking</p>

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1 generally. I'm asking with regard to  
2 DMF.

3 MS. DAVIDSON: Why don't you  
4 just rephrase it, then?  
5 Because --

6 MR. SLATER: I don't think I  
7 need to.

8 MS. DAVIDSON: We need clear  
9 questions.

10 MR. SLATER: Thank you for  
11 telling me my questions aren't  
12 clear.

13 BY MR. SLATER:

14 Q. Please answer, Doctor.

15 MS. DAVIDSON: I'm sorry,  
16 but you added a caveat after your  
17 question. At this point, I don't  
18 even know what the standing  
19 question is.

20 So I'm going to --

21 MR. SLATER: That's good  
22 because you're not the one who I'm  
23 actually deposing. So we're good.

24 MS. DAVIDSON: Adam, thank

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1 you. I object to your question as  
2 vague and --

3 MR. SLATER: I'll ask again,  
4 because you're going to -- you're  
5 going to have this conversation  
6 with me, and it's not going to  
7 really get us anywhere.

8 So I'll ask it again,  
9 Doctor.

10 BY MR. SLATER:

11 Q. What practices in the  
12 industry would you expect that ZHP  
13 followed with regard to the DMF that it  
14 purchased and used in the zinc chloride  
15 process?

16 A. ZHP would have -- ZHP would  
17 have effectively selected a supplier.  
18 ZHP would have signed an agreement with  
19 them. ZHP would have received a  
20 specification from them. ZHP would have  
21 then effectively developed the same  
22 analytical methods or similar analytical  
23 methods as them. ZHP would have  
24 effectively looked for how this solvent

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1 would remain in the process. And ZHP  
2 would have, at the beginning, when they  
3 were developing the process and  
4 follow-on, they would have used USP  
5 standards for residual solvents.

6 Q. When you say the spec would  
7 be received, is that the certificate of  
8 analysis?

9 A. The specification without  
10 being listed on the C of A, maybe.

11 Normally, the informations  
12 are communicated separate from the  
13 C of A. And a C of A would have been  
14 submitted as part of the specifications.

15 Q. You said something a few  
16 moments ago about whether there was a  
17 monograph for DMF.

18 If there was a monograph for  
19 DMF, would you expect that ZHP would have  
20 looked at the monograph to get  
21 information about the DMF?

22 MS. DAVIDSON: Objection.

23 THE WITNESS: I'm struggling  
24 with ZHP getting information from

Page 121

1 the monograph.

2 Could you please explain  
3 your question -- that question to  
4 me?

5 BY MR. SLATER:

6 Q. Sure.

7 A. I apologize.

8 Q. Sure.

9 You said just a few moments  
10 ago that you're not aware of a monograph  
11 for DMF.

12 Did I understand you  
13 correctly when you said that a few  
14 minutes ago?

15 A. Yes.

16 Q. Okay. All right.

17 MR. SLATER: We're going to  
18 put up a new exhibit, which is  
19 going to be Exhibit-6.

20 - - -

21 (Whereupon, Exhibit Afnan-6,  
22 No Bates, Concise International  
23 Chemical Assessment Document 31,  
24 was marked for identification.)



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1 - - -

2 BY MR. SLATER:

3 Q. This is a World Health

4 Organization document from 2001.

5 And as you can see, it's

6 titled, N,N-dimethylformamide.

7 Do you see that on the

8 screen?

9 A. Yes.

10 Q. I assume you've not seen

11 this before, based on the answer you gave

12 me a couple of questions ago that you had

13 not seen a monograph about DMF; is that

14 correct?

15 A. That's incorrect. I have

16 seen this. That's not a monograph.

17 Q. Okay. So let me -- let me

18 start over.

19 You've seen this document?

20 A. Yes.

21 Q. When did you see it?

22 A. During the course of my

23 reviews before writing my report.

24 Q. Let's go to Page 5.

Page 123

1 Looking at the bottom right

2 corner, the first full paragraph under

3 Section 2, titled, Identity and

4 Physical/Chemical Properties.

5 Do you see where I am on the

6 bottom right?

7 A. Yes.

8 Q. The first paragraph under

9 that heading, the last sentence says, DMF

10 sold commercially contains trace amounts

11 of methanol, water, formic acid and

12 dimethylamine.

13 And then there's a citation

14 to a publication from 1994.

15 Do you see that?

16 A. Yes.

17 Q. Did you see that when you

18 wrote your report?

19 A. As I said, I have seen the

20 report, yes. I've seen this document.

21 Yes.

22 Q. So you knew when you wrote

23 your report that according to a World

24 Health Organization publication about

Page 124

1 DMF, dated in 2001, the impurities of DMF

2 sold commercially include dimethylamine?

3 You would have seen that and known that

4 when you wrote your report, correct?

5 MS. DAVIDSON: Objection.

6 That's not what he said.

7 THE WITNESS: Can you

8 rephrase, please, or repeat?

9 BY MR. SLATER:

10 Q. When you wrote your

11 report --

12 A. Yes.

13 Q. -- you were aware that this

14 publication stated that DMF sold

15 commercially contains dimethylamine? You

16 knew that when you wrote your report,

17 right?

18 MS. DAVIDSON: Objection.

19 THE WITNESS: So here is my

20 response, right. This is a

21 general statement about DMF. The

22 challenge is going to be

23 multiple-fold.

24 One is, was there a USP or

Page 125

1 EP monograph for DMF? And the

2 answer is still no.

3 Did, effectively, every

4 batch of product they manufactured

5 have dimethylamine because of this

6 statement? That's a conclusion

7 that cannot be drawn.

8 Even if it is there, again,

9 if this is available to ZHP, then

10 why would the FDA say that neither

11 industry nor regulators knew about

12 the formation of NDMA's?

13 BY MR. SLATER:

14 Q. If ZHP had looked at

15 scientific literature and read this

16 document and seen that commercially sold

17 DMF contains trace amounts of

18 dimethylamine, they would have been on

19 notice of the potential for dimethylamine

20 to be introduced to the zinc chloride

21 process as an impurity of the DMF they

22 were purchasing; they would have been

23 aware of that possibility, correct?

24 MS. DAVIDSON: Objection.

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1 THE WITNESS: ZHP considered  
2 their process, looked at their  
3 materials, looked at what they  
4 were doing and assessed the  
5 process for unknown impurities  
6 which would cause problems,  
7 unknown impurities which would be  
8 mutagenic. And they came to the  
9 conclusion, based on the  
10 information they had, that that  
11 was not the case.  
12 So saying because of this  
13 document they should have known  
14 about dimethylamine, I don't know  
15 how that relates to assessment of  
16 the -- risk assessment of the  
17 manufacturing process. Because,  
18 again, this is not a document that  
19 one would go to if you are not  
20 manufacturing for WHO regions.  
21 MS. DAVIDSON: Is this a  
22 good time for a break?  
23 THE WITNESS: Yes.  
24 MR. SLATER: It's not,

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1 actually, because I have to do  
2 something at noon, so I'd rather  
3 go another ten minutes and then  
4 take a break at noon. I have to  
5 speak to somebody for about ten  
6 minutes.  
7 MS. DAVIDSON: Noon is in 16  
8 minutes, actually.  
9 MR. SLATER: I realize. I  
10 don't need to stop exactly at  
11 noon, but thank you for correcting  
12 my time count.  
13 MS. DAVIDSON: Dr. Afnan,  
14 would you like a break now or wait  
15 until noon?  
16 THE WITNESS: I would --  
17 MR. SLATER: We can't go for  
18 ten more minutes? I mean, come  
19 on.  
20 MS. DAVIDSON: I'm asking  
21 the witness.  
22 THE WITNESS: I would  
23 appreciate it, because my mouth is  
24 really dry and I need to drink

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1 something.  
2 MS. DAVIDSON: Okay. Let's  
3 go off the record.  
4 MR. SLATER: You don't have  
5 any water with you, Doctor?  
6 THE WITNESS: I've run out.  
7 MS. DAVIDSON: I'm sorry.  
8 I'm sorry. No, we're not doing  
9 this.  
10 MR. SLATER: You don't need  
11 to be so angry. It's not  
12 necessary to be so angry.  
13 MS. DAVIDSON: I'm not  
14 angry, Adam. I think you're the  
15 one who is angry.  
16 Let's take a seven-minute  
17 break, and then we can do a few  
18 minutes before your noon call.  
19 Let's go off the record.  
20 VIDEO TECHNICIAN: We're off  
21 the record at 11:45 a.m.  
22 - - -  
23 (Whereupon, a brief recess  
24 was taken.)

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1 - - -  
2 VIDEO TECHNICIAN: We're  
3 back on the record at 11:54 a.m.  
4 BY MR. SLATER:  
5 Q. In evaluating this case --  
6 actually, let me -- let me withdraw that.  
7 MR. SLATER: Do you have  
8 that document ready? Let's go to  
9 the next exhibit, which is  
10 Exhibit-7.  
11 - - -  
12 (Whereupon, Exhibit Afnan-7,  
13 No Bates, Dimethylformamide:  
14 Purification, Tests for Purity  
15 and Physical Properties, was  
16 marked for identification.)  
17 - - -  
18 BY MR. SLATER:  
19 Q. On the screen is Exhibit-7,  
20 a publication of the International Union  
21 of Pure and Applied Chemistry, titled,  
22 Dimethylformamide: Purification, Tests  
23 for Purity and Physical Properties.  
24 Do you see that?

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1 A. Yes.

2 Q. Have you ever seen this

3 document?

4 A. I do not recall. I don't

5 think so, but I don't recall.

6 Q. Let's go to Page 887,

7 please, the middle of the page.

8 You see in the middle of the

9 page there's two formulas? Just below

10 the first formula, do you see the word

11 "formic acid"?

12 A. Yes.

13 Q. Looking at the middle of the

14 page it says, Formic acid and

15 dimethylamine are thus predominant

16 impurities in DMF and determine the odor

17 of the impure solvent.

18 Do you see that?

19 A. Yes.

20 Q. So this would be another

21 publication, and just for the record,

22 this publication is from 1977, stating

23 that dimethylamine is a -- one of the

24 predominant impurities in DMF.

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1 That's what this says,

2 right?

3 A. Those are the words on the

4 screen.

5 Q. Based on the literature I've

6 shown you, would you agree with me that

7 ZHP should have been aware that the DMF

8 they were using in the zinc chloride

9 process could contain dimethylamine as an

10 impurity and could introduce the DMA to

11 the process as an impurity of the DMF?

12 Do you agree that ZHP should

13 have been aware of that possibility?

14 MS. DAVIDSON: I object.

15 This is outside the scope of his

16 opinions. He's not a chemist

17 here.

18 MR. SLATER: I'm not asking

19 a chemistry question.

20 BY MR. SLATER:

21 Q. I'm asking, from a GMP

22 perspective, should ZHP have been aware

23 of the potential introduction of the

24 dimethylamine to the zinc chloride

Page 132

1 process as an impurity of DMF?

2 MS. DAVIDSON: Based on the

3 two lines you read?

4 MR. SLATER: I'm not going

5 to go back-and-forth with you.

6 BY MR. SLATER:

7 Q. Please answer the question.

8 A. So ZHP investigated the

9 process with DMF and zinc chloride for

10 two years, okay? This was reported to

11 FDA, as well, after doing their research.

12 So based on the work they

13 did, based on the data, and based on the

14 verification review by FDA, and their

15 drug product manufacturing clients, the

16 question of should they have known or

17 not, the question of did they know about

18 the formation of NDMA, and the answer is

19 they did not know.

20 FDA also states that they

21 did not know. FDA says they do not know,

22 nor did industry, knew where these were

23 coming from.

24 Q. As a matter of GMP, was ZHP

Page 133

1 to understand -- rephrase.

2 As a matter of current good

3 manufacturing practices during the

4 development and use of the zinc chloride

5 process, was ZHP obligated, as a matter

6 of cGMP, to be aware that one of the

7 known impurities of commercially sold DMF

8 was dimethylamine?

9 Were they -- were they

10 required to at least be aware of that

11 fact in performing their risk assessment;

12 yes or no?

13 MS. DAVIDSON: Objection.

14 Lacks foundation.

15 THE WITNESS: ZHP would not

16 be looking at the research based

17 on publications. They would have

18 been looking at the research based

19 on what was happening in the

20 chemistry, in their -- in the

21 reactors, and the analytical

22 results they were getting, and

23 also based on the documentation

24 they were receiving from their

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1 suppliers. All of that was then  
2 run by FDA.  
3 So to say that here is a  
4 statement and because of this they  
5 should have taken that into  
6 consideration, I think it's a --  
7 it's an extrapolation of this to  
8 something else that was not there.  
9 ZHP looked at, effectively,  
10 the process, they developed it.  
11 They took two years. They ran  
12 multiple samples. They did  
13 extensive testing. Then they  
14 decided to change the process,  
15 which was then submitted to both  
16 FDA as well as EDQM, the European  
17 authority.  
18 BY MR. SLATER:  
19 Q. I just want to be clear.  
20 It's your opinion that ZHP,  
21 as part of its risk assessment, did not  
22 need to consult scientific literature at  
23 all with regard to potential risks of the  
24 substances they were using in their

Page 135

1 manufacturing processes for valsartan?  
2 MS. DAVIDSON: I'm going to  
3 object that that mischaracterizes  
4 his testimony. And it may be that  
5 you're mischaracterizing his  
6 testimony, because while he was  
7 answering you were --  
8 MR. SLATER: I don't know  
9 why you're giving a speech. You  
10 objected, I --  
11 MS. DAVIDSON: -- engaged in  
12 another conversation and not  
13 looking at the camera and  
14 listening to his answer.  
15 And that may be why you  
16 misheard it.  
17 MR. SLATER: Counsel, please  
18 don't make any more speaking  
19 objections today.  
20 BY MR. SLATER:  
21 Q. Can you answer the question,  
22 please?  
23 A. So, again, to repeat my  
24 answer -- to repeat my answer, ZHP looked

Page 136

1 at its chemical manufacturing process of  
2 zinc chloride and DMF as a catalyst and a  
3 solvent. ZHP took two years to develop  
4 that process. ZHP extensively tested  
5 that process and the products from that  
6 process. ZHP used the methodology -- the  
7 analytical methodology that was available  
8 to it. Documented it all, then submitted  
9 it to FDA.  
10 ZHP even made an engineering  
11 batch of -- of valsartan with the new  
12 process, submitted all of that to FDA.  
13 So with that body of  
14 evidence versus going and looking  
15 specifically in the universe of published  
16 literature for dimethylamine is not  
17 logical. So did they investigate? They  
18 did investigate.  
19 Q. And you agree with me, based  
20 on the testimony you've read and the  
21 stipulation you've read that was entered  
22 in this case, ZHP did not do scientific  
23 research in the literature with regard to  
24 potential impurities or degradation of

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1 DMF, correct?  
2 MS. DAVIDSON: Objection.  
3 BY MR. SLATER:  
4 Q. I understand you're saying  
5 they didn't need to do it.  
6 I'm just asking if you agree  
7 they did not do it?  
8 MS. DAVIDSON: Objection.  
9 THE WITNESS: I didn't say  
10 they didn't need to do it. You're  
11 mischaracterizing what I said.  
12 My statement, again, is that  
13 they did do sufficient risk  
14 assessments, sufficient assessment  
15 of the process, the zinc chloride  
16 process, before compiling the data  
17 and submitting it to the  
18 regulator.  
19 MR. SLATER: Let's go off  
20 the record.  
21 VIDEO TECHNICIAN: We're off  
22 the record at 12:04 p.m.  
23 - - -  
24 (Whereupon, a luncheon

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1 recess was taken.)  
2 - - -  
3 VIDEO TECHNICIAN: We're  
4 back on the record at 12:44 p.m.  
5 BY MR. SLATER:  
6 Q. You mentioned at one point  
7 that you were retained to respond to the  
8 plaintiff experts.  
9 Do you remember you told me  
10 that earlier?  
11 A. They -- the scope of my  
12 assignment was to effectively opine on  
13 the subjects which are -- or the topics  
14 which are raised against ZHP, yes.  
15 Q. And did you understand your  
16 role to be to, in essence, defend ZHP  
17 against these accusations?  
18 MS. DAVIDSON: I'm sorry, I  
19 was on mute.  
20 I'm objecting to that  
21 question.  
22 Court reporter, can you read  
23 that question back?  
24 - - -

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1 (Whereupon, the court  
2 reporter read the following part  
3 of the record:  
4 "Question: And did you  
5 understand your role to be to, in  
6 essence, defend ZHP against these  
7 accusations?")  
8 - - -  
9 MS. DAVIDSON: Yeah, that's  
10 a very objectionable question. So  
11 I'm doubling my objection.  
12 MR. SLATER: I'll ask the  
13 question differently.  
14 BY MR. SLATER:  
15 Q. Did you understand your role  
16 to be to come up with arguments to defend  
17 ZHP?  
18 MS. DAVIDSON: Same  
19 objections.  
20 THE WITNESS: That was not  
21 how I have approached this.  
22 My approach to this is,  
23 there are statements made by  
24 plaintiff experts, assess them

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1 for -- for correctness. And, at  
2 the same time, look at the -- you  
3 know, see what is being said and  
4 whether there is -- whether that  
5 is correct or not. Yeah.  
6 BY MR. SLATER:  
7 Q. Let's go back to the  
8 document that we had up before. We're  
9 back in Exhibit-7 now.  
10 Looking at Page 887, where  
11 it says, Formic acid and dimethylamine  
12 are, thus, predominant impurities in DMF  
13 and determine the odor of the impure  
14 solvent.  
15 My question is, do you  
16 understand what that means when this  
17 document and this publication says that  
18 dimethylamine is a predominant impurity  
19 in DMF? Do you understand what that  
20 means?  
21 MS. DAVIDSON: Objection.  
22 THE WITNESS: How is  
23 "predominant" qualified?  
24 BY MR. SLATER:

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1 Q. You see the words on the  
2 page, I'm asking if you understand what  
3 that means.  
4 A. Okay. So I'm looking at the  
5 word "predominant impurities," and I  
6 would want to know what sort of a  
7 percentage impurity that is.  
8 Q. Why does that matter?  
9 A. So there are no 100 percent  
10 pure compounds in manufacturing grade  
11 and, therefore, it is relevant because  
12 it's a case of -- this is a -- this is a  
13 scientific hypothetical statement, that  
14 when you make this with this you have two  
15 impurities or two of the degradation  
16 products; the thermo degradation produces  
17 this and this.  
18 What is lacking in the  
19 statement and, respectfully, in your  
20 question, there is no information about  
21 what the thermal conditions are, nor  
22 about what the percentages or what the  
23 levels of those two degradation products  
24 are.



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1 Q. Was ZHP required to assess  
2 the potential risks of potential  
3 impurities that could be introduced to  
4 the manufacturing process by the  
5 substances that ZHP was using?  
6 A. Can you repeat, please?  
7 Q. Was ZHP supposed to assess  
8 the potential risks from the potential  
9 impurities that could be introduced to  
10 the valsartan manufacturing process?  
11 We're talking about the zinc  
12 chloride process here. Let's talk about  
13 that.  
14 A. So ZHP, as per practice and  
15 regulations, would have been looking and  
16 would have needed to demonstrate looking  
17 for potential impurity formations. And,  
18 effectively, they would have needed to  
19 validate it, which they did.  
20 And then submit it to the  
21 regulator, which they did. And the  
22 regulator agreed with their assessment at  
23 the time.  
24 So what they were supposed

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1 to do they did do, and the regulator  
2 agreed with that assessment.  
3 Q. So you agree that ZHP was  
4 required, as part of its assessment, to  
5 assess the potential risks from the  
6 potential impurities that could be  
7 introduced to the zinc chloride process  
8 from the substances that were being used;  
9 you agree with that, correct?  
10 MS. DAVIDSON: Objection.  
11 THE WITNESS: I responded to  
12 that. I don't know how to respond  
13 again.  
14 BY MR. SLATER:  
15 Q. Well, you did, Doctor, just  
16 what I heard was you told me what they  
17 did and what regulators did. And I  
18 literally did not ask you about what  
19 anyone else did. I asked what would they  
20 do. I asked what they were supposed to  
21 do.  
22 I just want to know if they  
23 were supposed to look at that or not?  
24 MS. DAVIDSON: Okay. So

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1 first of all --  
2 MR. SLATER: I don't need a  
3 lecture. You can object to the  
4 question. You have an objection  
5 to form. He can answer.  
6 You are not allowed to give  
7 a speaking objection. Please  
8 don't.  
9 MS. DAVIDSON: Adam, you  
10 have given speaking objections  
11 endlessly in the last two weeks.  
12 MR. SLATER: I'm asking you  
13 to not to do another speaking  
14 objection. Can you just please  
15 let him answer the question?  
16 MS. DAVIDSON: No. No.  
17 Because, Adam --  
18 MR. SLATER: So don't let  
19 him answer. You're going to give  
20 a speech. Go ahead. Give a  
21 speech.  
22 MS. DAVIDSON: Adam, you  
23 interrupted Dr. Afnan. And as you  
24 know, that is not appropriate

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1 deposition behavior. Then when I  
2 tried to explain that you were  
3 interrupting Dr. Afnan, you  
4 proceeded to interrupt me. So  
5 you've now interrupted both of us  
6 in the course of this. I was not  
7 appreciative of that.  
8 Please allow the witness to  
9 finish answering questions he's  
10 asked. Please do not interrupt  
11 him.  
12 I would object if there were  
13 a question pending, but I don't  
14 even know what question is pending  
15 now. Because, basically, the  
16 witness started to answer the  
17 question and you berated --  
18 interrupted and berated him.  
19 So why don't we have the  
20 court reporter read back the  
21 question, and why doesn't  
22 Dr. Afnan provide a complete  
23 answer?  
24 MR. SLATER: I'm not going

Page 146

1 to -- I'm going to ask the  
2 question again myself.  
3 BY MR. SLATER:  
4 Q. So, Dr. Afnan, do you agree  
5 that ZHP was required to assess the  
6 potential risks from the potential  
7 impurities that could be introduced to  
8 the zinc chloride process by the  
9 substances that ZHP was using; yes or no?  
10 A. ZHP did do that. So yes.  
11 But they did do that.  
12 Q. I didn't ask if they did it.  
13 I asked if they were supposed to do that.  
14 Can you just answer that  
15 question, please?  
16 A. I did answer.  
17 MS. DAVIDSON: Objection.  
18 Objection. Asked and answered.  
19 BY MR. SLATER:  
20 Q. Doctor, I would  
21 appreciate --  
22 MS. DAVIDSON: You cannot  
23 control the way he answers a  
24 question. You can't, like, tell

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1 him to repeat his question and cut  
2 off half the answer. Come on.  
3 BY MR. SLATER:  
4 Q. Doctor, I'm not asking you  
5 what ZHP actually did.  
6 I asked you if they were  
7 supposed to evaluate the potential risks  
8 from the potential impurities that could  
9 be introduced to the zinc chloride  
10 process by the substances that ZHP was  
11 using.  
12 I just want to know if  
13 that's something they were supposed to  
14 do. I'm not asking if they did it or  
15 not.  
16 Can you please answer that  
17 question?  
18 MS. DAVIDSON: Objection.  
19 Compound. And asked and answered.  
20 THE WITNESS: ZHP did what  
21 it was supposed to do.  
22 BY MR. SLATER:  
23 Q. I'm sorry. Can you answer  
24 my question, please?

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1 A. I did.  
2 Q. I'm not asking you what ZHP  
3 did. So I'm not sure why you're  
4 insisting on continually saying what ZHP  
5 did.  
6 I asked what they were  
7 supposed to do. I didn't ask if they did  
8 it or not.  
9 So can you please answer my  
10 question?  
11 MS. DAVIDSON: I'm going to  
12 object again. Asked and answered.  
13 Compound question. Badgering the  
14 witness.  
15 THE WITNESS: ZHP did what  
16 it was supposed to do.  
17 BY MR. SLATER:  
18 Q. Please answer my question.  
19 I'm not asking what ZHP did.  
20 Can you please answer my  
21 question about what they were supposed to  
22 do?  
23 MS. DAVIDSON: Objection.  
24 We can stay on this all day if you

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1 want. It's been asked and  
2 answered multiple times.  
3 THE WITNESS: Yep. Yep.  
4 BY MR. SLATER:  
5 Q. I'm sorry, Doctor, that  
6 doesn't substitute for your answer. Just  
7 because counsel keeps talking and saying  
8 things. You have to actually answer the  
9 questions, under oath, yourself.  
10 A. I answered the question that  
11 was asked, Mr. Slater.  
12 My answer to you was ZHP  
13 followed the regulations, followed the  
14 GMPs, which sets the expectations, and  
15 carried out those activities.  
16 Q. I keep telling you I'm not  
17 asking what ZHP did. I don't know why  
18 you keep telling me what ZHP did.  
19 Am I not communicating  
20 clearly?  
21 MS. DAVIDSON: Objection.  
22 I'm going to instruct you not to  
23 answer that question. That is  
24 not -- that is a rhetorical

question. You're badgering the witness.

Come on, Adam, just ask your questions and that's that. Don't badger the witness.

MR. SLATER: I don't really want to talk directly with you at this point about this. I really just want to explain to him, since it's his first deposition, that when I keep asking one question and he keeps talking about something I'm not asking, I find it to be, you know, a little bit frustrating. I'm not yelling. I'm talking in a normal tone of voice.

And I don't understand why he keeps telling me what they did when I've said, like, six times in a row, I'm not asking what they did. I'm asking what they're supposed to do.

So I'm starting -- I'm

that could be introduced to the zinc chloride process by the substances that ZHP was using?

I want to know if they were supposed to do that. I'm not asking what they did. I'm asking if they were supposed to do so.

Can you please answer that question?

MS. DAVIDSON: Objection. Vague. Asked and answered.

Dr. Afnan, do you want the question read back by the court reporter?

THE WITNESS: Sure.

MR. SLATER: You need the question read back?

THE WITNESS: Yes, please.

BY MR. SLATER:

Q. Was ZHP required to assess the potential risks that could be introduced due to potential impurities from the substances used in the zinc chloride process; yes or no?

feeling like he won't answer my question deliberately, which doesn't feel good.

So I'll give it one last shot, and then we'll mark this part of the transcript.

BY MR. SLATER:

Q. Doctor, I'm not asking you what ZHP did. I'm asking if they were supposed to do what I asked you.

Can you just answer that question, please?

MS. DAVIDSON: Objection. Vague. Asked and answered. Mischaracterizes his testimony.

I think that's it.

THE WITNESS: Can you read back the question that you keep asking me, which I believe I have answered?

BY MR. SLATER:

Q. Here is the question: Was ZHP required to evaluate and assess the potential risks from potential impurities

MS. DAVIDSON: Objection. Vague. Asked and answered.

THE WITNESS: ZHP looked at the potential risks due to the potential impurities in the process, referring to the zinc chloride process, and came to a conclusion, which was reported to FDA.

ZHP did do what it was supposed to do.

BY MR. SLATER:

Q. Did I ask you what ZHP did in that question?

MS. DAVIDSON: Objection. That's not a question to answer.

MR. SLATER: It actually is a question.

BY MR. SLATER:

Q. Please answer.

MS. DAVIDSON: No.

BY MR. SLATER:

Q. Doctor, did I ask you what ZHP did or did I ask you, as I have,

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1 like, multiple times, asked you what they  
2 were supposed to do?

3 MS. DAVIDSON: Objection.

4 BY MR. SLATER:

5 Q. I mean, is my question not  
6 clear? Are you not understanding my  
7 question? If you're not then I can, you  
8 know, rephrase it.

9 MS. DAVIDSON: Adam, every  
10 time I object you just badger the  
11 witness more. And so I don't even  
12 know what question is pending.

13 And I'm objecting to your  
14 follow-on badgering of the witness  
15 following the badgering of the  
16 witness I already objected to.

17 THE WITNESS: You want a  
18 yes-or-no answer from me. I am  
19 not able to give you a yes-or-no  
20 answer, because I think the  
21 question has no merit of a  
22 yes-or-no answer -- or the answer  
23 has no merit if it's a yes-or-no  
24 answer.

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1 I believe I have answered  
2 the question multiple times in  
3 exact same manner and have  
4 addressed the question you have  
5 asked me.

6 BY MR. SLATER:

7 Q. Let's go now to Page 890 of  
8 that document. Same document we've been  
9 in, which is Exhibit-7. The very top.

10 At the top of Page 890, it  
11 says, Tests for purity. Owing to its  
12 various modes of degradation, hydrolysis,  
13 thermal and photochemical decomposition,  
14 the principal impurities found in DMF  
15 are: dimethylamine, formic acid,  
16 hydrogen cyanide, carbon dioxide and  
17 carbon monoxide.

18 Do you see that?

19 A. I see it, yes.

20 Q. In forming your opinions in  
21 this case, did you take into account the  
22 fact that DMF could degrade through  
23 hydrolysis and due to thermal impact,  
24 meaning temperature?

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1 Did you take that into  
2 account, that those were both pathways to  
3 degradation that could yield  
4 dimethylamine?

5 MS. DAVIDSON: Objection.

6 THE WITNESS: Dr. Xue, who  
7 is a synthesis organic chemist, a  
8 respected lecturer at University  
9 of Maryland, addresses those  
10 issues -- those points, in his  
11 testimony.

12 The thermal decomposition  
13 that you have asked me about and  
14 is on the screen is effectively  
15 based on reaching a particular  
16 temperature which the process was  
17 never at.

18 So if that temperature is  
19 not reached and if hydrolysis is  
20 not taking place, because it's  
21 neither acidic or basic, then --  
22 the question of did I take that  
23 into account? The answer is, yes,  
24 I did take that into account.

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1 BY MR. SLATER:

2 Q. Did you form your own  
3 independent opinion about what you just  
4 told me, or were you relying on Dr. Xue's  
5 analysis of that subject matter?

6 A. Dr. Xue refers to two  
7 statements. One is about the boiling  
8 point of DMF, which I have referenced him  
9 and verified by looking at, effectively,  
10 the boiling point of DMF. I've also  
11 looked at the pH of the process, which,  
12 again, he refers to, and, again, I have  
13 verified.

14 So is it my opinion or is it  
15 his opinion? It's my opinion.

16 Q. And you are not an expert in  
17 the field of organic chemistry, right?

18 A. I am --

19 MS. DAVIDSON: Objection.  
20 Objection. You literally  
21 objected, Adam, last week every  
22 single time I asked somebody if  
23 they were an expert in something.

24 MR. SLATER: I'll ask the

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1 question differently.  
2 BY MR. SLATER:  
3 Q. You told me before that you  
4 are not holding yourself out as an expert  
5 in organic chemistry.  
6 Have you changed your mind  
7 on that?  
8 A. I have a degree in  
9 chemistry. I have a Ph.D. in chemistry.  
10 I am not a synthetic organic  
11 chemist and up to date, but I do  
12 understand sufficiently about chemistry  
13 to opine on the subject.  
14 Q. In the materials you  
15 reviewed, did you see whether ZHP tested,  
16 at any time, to see if DMF could degrade  
17 and yield dimethylamine under the  
18 conditions used in the zinc chloride  
19 process?  
20 MS. DAVIDSON: Objection.  
21 THE WITNESS: So if I go to  
22 my report, I think the answer is  
23 there.  
24 Number 169, it says, and

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1 it's the third line, But as  
2 Mr. Dong explains, this was  
3 because both sodium azide and  
4 sodium nitrate had been used  
5 before the process changed, and  
6 ZHP concluded, through the risk  
7 assessment process, that the  
8 increased amount of these  
9 substances did not significantly  
10 increase the potential risk of  
11 sodium azide or sodium nitrate.  
12 Moreover, even though ZHP had  
13 concluded the potential risk was  
14 low, it still conducted testing to  
15 determine residual amounts of  
16 those substances and performed a  
17 further risk assessment based on  
18 that testing.  
19 So they did look at what was  
20 going on.  
21 BY MR. SLATER:  
22 Q. I just asked you whether  
23 ZHP, to your knowledge, ever performed  
24 any tests to determine whether DMF could

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1 degrade and give off dimethylamine under  
2 the conditions of the zinc chloride  
3 process.  
4 Do you know whether they did  
5 or not? Did they perform any test on  
6 that?  
7 MS. DAVIDSON: Objection.  
8 THE WITNESS: I don't recall  
9 whether they did any tests or not.  
10 However, the common practice  
11 of industry would have been to  
12 effectively look at known  
13 solvents. And this was a known  
14 solvent.  
15 The risk assessment would  
16 have occurred -- the assessment  
17 that you are asking would have  
18 occurred during development phases  
19 and not during commercial  
20 manufacture.  
21 The development phases were  
22 done at a different site and they  
23 were investigated and studied over  
24 the course of more than two years.

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1 BY MR. SLATER:  
2 Q. Can you answer my question,  
3 please?  
4 A. I answered your question,  
5 which was, did they look at this test,  
6 did they test for this?  
7 And my answer is still, ZHP  
8 looked at the new process, the zinc  
9 chloride process with DMF, over a period  
10 of longer than two years in the  
11 development workshop at a different site.  
12 And they concluded that the  
13 process was not generating anything  
14 undesirable, so.  
15 Q. Could you please answer my  
16 question?  
17 MS. DAVIDSON: Objection.  
18 THE WITNESS: I answered the  
19 question.  
20 ZHP, over two years,  
21 investigated the raw materials and  
22 the process at their development  
23 site and reported that data.  
24 BY MR. SLATER:



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1 Q. Can you answer my question,  
2 please?

3 MS. DAVIDSON: Objection.  
4 You're badgering the witness.  
5 He's answered your question to the  
6 best of his ability.

7 BY MR. SLATER:  
8 Q. Please answer.  
9 MS. DAVIDSON: Objection.  
10 THE WITNESS: ZHP -- ZHP  
11 tested all the raw materials and  
12 the product from the process in  
13 their development facility over a  
14 period of greater -- longer than  
15 two years.

16 BY MR. SLATER:  
17 Q. Did ZHP ever, to your  
18 knowledge, ever do a test to determine  
19 whether, under the conditions of the zinc  
20 chloride process, DMF could degrade and  
21 give off dimethylamine; yes or no?  
22 Was that specific test ever  
23 done by ZHP, to your knowledge?  
24 MS. DAVIDSON: Objection.

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1 Asked and answered.  
2 THE WITNESS: I have  
3 answered the question twice or  
4 three times.  
5 So did ZHP ever do it? As  
6 I've said, they did it in their  
7 development facility. In a  
8 commercial setting, it would be  
9 against the GMPs to begin to do  
10 tests on the site for whatever  
11 reason, whatever purpose.

12 BY MR. SLATER:  
13 Q. Your testimony is that as  
14 part of the risk assessment, ZHP  
15 performed a specific test to determine  
16 whether DMF could degrade and give off  
17 dimethylamine under the conditions of the  
18 zinc chloride process?  
19 It's your understanding they  
20 actually did that test as part of the  
21 risk assessment; do I understand you  
22 correctly?  
23 MS. DAVIDSON: Objection.  
24 Asked and answered.

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1 Mischaracterizes testimony.  
2 Badgering the witness.  
3 THE WITNESS: That's not  
4 what I said. What I said was,  
5 they -- raw materials that were  
6 being used in the process were  
7 reviewed, were assessed, were risk  
8 assessed, for ensuring that the  
9 process was safe.  
10 MR. SLATER: Let's take that  
11 exhibit down. And let's go back  
12 to the deviation investigation  
13 report, please. Page 170.  
14 MS. DAVIDSON: What exhibit  
15 number was that again? Could  
16 someone remind me?  
17 MR. SLATER: I don't  
18 remember. It's either Exhibit-5  
19 or 6. Why don't we find out.  
20 Exhibit-5.  
21 Actually, let's start off --  
22 yeah. Okay. That's good.

23 BY MR. SLATER:  
24 Q. Looking at page --

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1 MR. SLATER: Actually, you  
2 know what, Chris, let's go back.  
3 Let's go to Page 9, actually.  
4 Sorry about that.

5 BY MR. SLATER:  
6 Q. Okay. We're looking now at  
7 Page 9 of Exhibit-5, the deviation  
8 investigation report.  
9 And I'd like to look  
10 starting in the middle of the page. And  
11 it says, For further confirmation, the  
12 following lab scale trials were designed  
13 and performed to verify the concluded  
14 formation mechanism of NDMA. The amount  
15 of NDMA formed by quenching under  
16 different temperatures is shown in the  
17 table below.  
18 Have you seen this page and  
19 taken this into account in forming your  
20 opinions in this case?  
21 A. Yes.  
22 Q. So you were aware that, as  
23 part of their deviation investigation,  
24 ZHP actually did lab tests where they had

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1 DMF at the same temperature for the same  
2 time period as under the zinc chloride  
3 process and then, after that, combined  
4 the sodium nitrate and they proved that  
5 NDMA resulted; so you're aware of that,  
6 correct?

7 MS. DAVIDSON: Objection.  
8 THE WITNESS: This document  
9 that you're looking at has some  
10 differences from the commercial  
11 scale batch.  
12 If you are looking at Rows  
13 Number 1 and 2, it's actually  
14 saying the pH is adjusted to 1.  
15 So the commercial process  
16 was not operating at pH of 1,  
17 number one.  
18 Number two, this is a test  
19 where they are driving to make  
20 NDMA. They are not trying to make  
21 valsartan, they are trying to make  
22 NDMA in the valsartan process.  
23 Point three, this document  
24 is after they have identified

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1 NDMA. This document, this  
2 deviation investigation, is  
3 actually trying to find the root  
4 cause of NDMA formation, and  
5 they're trying various process  
6 parameters to see what results  
7 would come from that. This is  
8 then reported to FDA.  
9 BY MR. SLATER:  
10 Q. All I asked you is if you  
11 knew this information when you wrote your  
12 report.  
13 Is the answer yes or no?  
14 MS. DAVIDSON: Objection.  
15 THE WITNESS: Did I read the  
16 investigation report, yes.  
17 BY MR. SLATER:  
18 Q. And this showed that when  
19 DMF was heated to 135 degrees Celsius for  
20 20 hours, it created dimethylamine, which  
21 then later combined with the sodium  
22 nitrate and NDMA was formed, correct?  
23 That's what this lab test shows, right?  
24 A. This lab test shows that if

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1 DMF, at 135 degrees, okay, 20 hours, then  
2 add MTB, water, sodium nitrate and adjust  
3 to 1 and then quench it as zero degrees  
4 and quench it at 10 and quench it at 20  
5 degrees.  
6 So it's different settings  
7 to generate or to create NDMA. That's  
8 what this document says.  
9 I don't see any statement  
10 about dimethylamine.  
11 Q. How would the NDMA have  
12 formed if the DMF didn't introduce the  
13 dimethylamine?  
14 A. That is --  
15 MS. DAVIDSON: Objection.  
16 BY MR. SLATER:  
17 Q. You're the -- you said  
18 you're a chemistry expert now, so tell  
19 me -- let me ask the question  
20 differently.  
21 How did the NDMA --  
22 rephrase.  
23 You see the fourth column,  
24 it says, NDMA in parts per million? Do

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1 you see that?  
2 A. Yes.  
3 Q. How did that NDMA form?  
4 MS. DAVIDSON: Objection.  
5 That's outside the scope of his  
6 opinions.  
7 MR. SLATER: When you say  
8 that, so I know how to take the  
9 deposition, are you saying he's  
10 not giving chemistry opinions?  
11 Because he just said a few minutes  
12 ago he is. So I need to  
13 understand what's in and what's  
14 out.  
15 MS. DAVIDSON: I didn't hear  
16 him say he's giving chemistry  
17 opinions. I think you're  
18 mischaracterizing his testimony  
19 now.  
20 I will let the witness speak  
21 for himself.  
22 THE WITNESS: I did not say  
23 that I was giving chemistry  
24 opinions. I said I do have a

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<p>1 chemistry background.</p> <p>2 My expertise in this is</p> <p>3 GMPs. And, again, to re-tread the</p> <p>4 point, I look at that screen and</p> <p>5 that tells me about the various</p> <p>6 conditions ZHP created to see what</p> <p>7 the -- you know, what levels of</p> <p>8 NDMA are formed.</p> <p>9 BY MR. SLATER:</p> <p>10 Q. Do you have any</p> <p>11 understanding as to how that NDMA formed</p> <p>12 in those lab tests, which you read about</p> <p>13 before you authored your report?</p> <p>14 MS. DAVIDSON: Objection.</p> <p>15 BY MR. SLATER:</p> <p>16 Q. It's a yes or no. Either</p> <p>17 you know or you don't.</p> <p>18 MS. DAVIDSON: Objection. I</p> <p>19 apologize for objecting in the</p> <p>20 middle of your questions. I</p> <p>21 always think they're done and then</p> <p>22 there's a postscript.</p> <p>23 THE WITNESS: My role, my</p> <p>24 remit, was to look at the</p>	<p>1 According to the deviation investigation</p> <p>2 report, DCE18001, in tetrazole formation</p> <p>3 of crude step, DMF is used as solvent and</p> <p>4 zinc chloride is used as catalyst. Since</p> <p>5 the temperature might reach 135, plus or</p> <p>6 minus 5 degrees Celsius, and the reaction</p> <p>7 time period last for 20, plus or minus</p> <p>8 one hour, dimethylamine might be formed</p> <p>9 by decomposition of DMF.</p> <p>10 Do you see what I just read?</p> <p>11 A. Yes.</p> <p>12 Q. Do you disagree with that</p> <p>13 conclusion that was drawn by ZHP in its</p> <p>14 deviation investigation report that I</p> <p>15 just read to you?</p> <p>16 A. This is not a conclusion,</p> <p>17 because it's saying it's a probable root</p> <p>18 cause. It's using the word -- the</p> <p>19 language, which says, and the reaction,</p> <p>20 it might be formed. That's not an, it is</p> <p>21 formed.</p> <p>22 This, as a deviation report,</p> <p>23 if submitted, which says it might be</p> <p>24 formed, my response would be, tell me</p>
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<p>1 plaintiff experts and assess</p> <p>2 GMP -- GMP statements.</p> <p>3 I was not here, on this</p> <p>4 project, to assess the chemistry.</p> <p>5 For that, there was Professor Xue.</p> <p>6 What I'm looking at and what</p> <p>7 you asked me about this</p> <p>8 is whether, you know,</p> <p>9 dimethylamine is formed. And I'm</p> <p>10 saying, I don't see it on the</p> <p>11 screen.</p> <p>12 BY MR. SLATER:</p> <p>13 Q. Do you doubt the results of</p> <p>14 these tests for any reason as they're</p> <p>15 documented in this report from ZHP?</p> <p>16 A. I have no evidence to doubt</p> <p>17 these results. And these were the</p> <p>18 results which were also submitted to FDA.</p> <p>19 So, no, I don't doubt the</p> <p>20 results.</p> <p>21 Q. Let's go to Page 170 of that</p> <p>22 document, please.</p> <p>23 Looking now at the middle of</p> <p>24 the page, ZHP states in this report,</p>	<p>1 whether it is or it isn't.</p> <p>2 And, again, this document is</p> <p>3 with hindsight. This document is being</p> <p>4 used to assess and to find the different</p> <p>5 pathways.</p> <p>6 Now, it also says, if the</p> <p>7 temperature -- it says, the temperature</p> <p>8 might reach 135, plus or minus 5 degrees.</p> <p>9 That information would be available in</p> <p>10 the batch report.</p> <p>11 Q. Did you evaluate that issue</p> <p>12 at all, what temperatures were reached</p> <p>13 and what impact that could have on the</p> <p>14 DMF?</p> <p>15 A. Again, my remit here was not</p> <p>16 chemistry.</p> <p>17 Q. As a GMP expert, one of your</p> <p>18 rolls -- one of the things -- rephrase.</p> <p>19 As a GMP expert, one of the</p> <p>20 things you needed to consider was what</p> <p>21 tests were performed by ZHP to determine</p> <p>22 whether they performed tests that were</p> <p>23 required by cGMP; that was within the</p> <p>24 scope of what you were doing, right?</p>

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1 MS. DAVIDSON: Objection.  
2 THE WITNESS: So the tests  
3 which are required to be performed  
4 for release of material are  
5 defined as per USP. So those are  
6 the tests which are there.

7 BY MR. SLATER:

8 Q. Looking at the paragraph  
9 that I was just reading in, it continues,  
10 In subsequent step, when using sodium  
11 nitrite to quench redundant azide,  
12 valsartan was not separated.

13 Do you understand what that  
14 sentence means?

15 MS. DAVIDSON: Objection.

16 THE WITNESS: So the  
17 valsartan was not separated, as it  
18 didn't settle out.

19 BY MR. SLATER:

20 Q. The next sentence says --  
21 rephrase.

22 Looking at the paragraph in  
23 the middle of the page, after the first  
24 couple of sentences about the formation

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1 of dimethylamine, it states, In  
2 subsequent step when using sodium nitrite  
3 to quench redundant azide, valsartan was  
4 not separated. Thus, trace amount of  
5 NDMA is formed by reaction between  
6 dimethylamine and nitrous acid. To  
7 verify this conclusion, Huahai conducted  
8 simulation tests in the laboratory to  
9 demonstrate the DMF degradation and the  
10 generation of NDMA, the detail is in  
11 Table 4-40 as follows.

12 Do you see what I just read?

13 A. I see what you just read.

14 Q. Did you read that when you  
15 wrote your report? Had you read that  
16 information I just read to you?

17 A. I have read this before I  
18 wrote my report, yes.

19 Q. Did you factor that into the  
20 opinions you offered on GMP in this case;  
21 yes or no?

22 MS. DAVIDSON: I really -- I  
23 guess if you're asking simply  
24 about GMP, that's fine. I really

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1 think you're delving into  
2 chemistry at this point, which are  
3 questions that are more  
4 appropriately asked to Professor  
5 Xue, who you already deposed.

6 But if you're just asking  
7 about his GMP opinions, that's  
8 fine.

9 THE WITNESS: So can you ask  
10 your question, please?

11 BY MR. SLATER:

12 Q. When you formed your  
13 opinions in this case regarding cGMP, did  
14 you take this information into account  
15 that I just read to you?

16 I just want to know if you  
17 took it into account when you formed your  
18 opinions; yes or no?

19 MS. DAVIDSON: Objection.

20 BY MR. SLATER:

21 Q. And, by the way, Doctor, I'm  
22 not asking for what the analysis was.  
23 I'm just asking if you took it into  
24 account.

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1 MS. DAVIDSON: I really  
2 think we need to have one question  
3 pending, one question answered,  
4 because you just said six  
5 different things.

6 BY MR. SLATER:

7 Q. You can answer.

8 A. The challenge that I have  
9 answering your complex and multiple  
10 questions is you say, did I take this  
11 into account when making my GMP  
12 decisions?

13 This is an investigation,  
14 which is happening in a lab, in a lab  
15 setting, as a result of a deviation which  
16 has taken place before these activities  
17 were taking place, before these -- this  
18 data was being generated.

19 The reason the data was  
20 generated was to actually push the  
21 process to certain limits and see what  
22 the impact is. This is not happening in  
23 a GMP setting, even though it's a  
24 deviation investigation for a GMP



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1 deviation.

2 These are happening in a  
3 development setting to try and address,  
4 to try and understand how NDMA is formed.

5 So when you ask me straight  
6 questions expecting a yes-or-no answer, I  
7 struggle.

8 Q. When you formed your  
9 opinions regarding whether or not ZHP  
10 complied with cGMPs, was this information  
11 that I just read to you something that  
12 you factored into your opinion?

13 Either it's yes or no or you  
14 can say something like, it was  
15 irrelevant, I didn't have to consider it.

16 I don't know what your  
17 answer is, but I'd just like to know if  
18 it was something that you relied on, in  
19 part, in forming your opinions.

20 MS. DAVIDSON: I'm going to  
21 object. Asked and answered.

22 THE WITNESS: I have  
23 answered this question.

24 And when I'm reading this,

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1 this is about an event which is  
2 after GMP manufacturing has  
3 stopped. ZHP stopped manufacture  
4 of valsartan in June. This is  
5 happening sometime later, much  
6 later; and they're looking at it.

7 This is not what was  
8 happening in their GMP area. So  
9 for me to look at this and look at  
10 this data and to draw a conclusion  
11 based on what was going on  
12 beforehand would actually not be  
13 correct.

14 BY MR. SLATER:

15 Q. You see in the Table 4-40 it  
16 documents that, under these conditions  
17 DMA was a degradation product of the DMF  
18 under these conditions, correct? That's  
19 what's documented on the table, correct?

20 A. I see what the table says.

21 Q. If ZHP had wanted to, they  
22 could have run the same or similar lab  
23 tests as part of their risk assessment  
24 before they started manufacturing with

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1 the zinc chloride process, right?

2 A. This is happening with  
3 hindsight, with effectively looking at --  
4 it's looking at what is happening in back  
5 end of 2018 and not what was happening  
6 early on.

7 Early on, when they were  
8 developing the process, ZHP had no reason  
9 to vary the process parameters, as per  
10 what's on the screen, and look for  
11 formation of NDMA. Point one.

12 Point two, as testified --  
13 or as stated by FDA, neither industry nor  
14 the regulators knew about the chemical  
15 pathways that would form NDMAs.

16 Point three, again, as is  
17 stated by FDA, neither industry nor  
18 regulators had the methods to detect  
19 NDMA. Dr. Gottlieb specifically says,  
20 NDMA is difficult to detect and to  
21 isolate.

22 So I look at this and this  
23 is all after the event. This is with  
24 hindsight. ZHP would not have known.

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1 And, again, if ZHP -- the  
2 fact that ZHP did not know about the  
3 formation of NDMAs is, again, stated by  
4 the regulator. The regulators didn't  
5 know that these processes would result in  
6 NDMA.

7 MR. SLATER: We can take  
8 that document down now and go to a  
9 different document.

10 Is it 8 now, right? Did you  
11 put it up? You were waiting for  
12 me and I was waiting for you.

13 MS. DAVIDSON: So we're  
14 marking this as Exhibit-8?

15 MR. SLATER: We are.

16 - - -

17 (Whereupon, Exhibit Afnan-8,  
18 No Bates, 4/1/15 General Notices  
19 and Requirements, was marked for  
20 identification.)

21 - - -

22 MR. SLATER: Can you reduce  
23 it just so the whole document is  
24 on the page? Yeah. Perfect.



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1 BY MR. SLATER:  
2 Q. So what we have on the  
3 screen as Exhibit-8 is an April 1, 2015,  
4 bulletin from the United States  
5 Pharmacopeia convention titled, General  
6 Notices and Requirements.  
7 Do you see that?  
8 A. Yes.  
9 Q. Do you know what USP is?  
10 A. Yes.  
11 Q. What is USP?  
12 A. USP is a not-for-profit  
13 independent organization that effectively  
14 writes two types of monographs. One is a  
15 general chapter, which is binding. And  
16 the other, which are not binding. So  
17 they write the specifications.  
18 Q. When you say "they write the  
19 specifications," what specifications?  
20 A. APIs, drug products, some  
21 raw materials.  
22 Q. Let's go to Page 4, please.  
23 And I'm looking now under  
24 Section 5.60, titled, Impurities and

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1 Foreign Substances.  
2 Do you see that?  
3 A. Yes.  
4 Q. This says, Tests for the  
5 presence of impurities and foreign  
6 substances are provided to limit such  
7 substances to amounts that are  
8 unobjectionable under conditions in which  
9 the article is customarily employed.  
10 Do you see what I just read?  
11 A. Yes.  
12 Q. Next this states,  
13 Non-monograph tests and acceptance  
14 criteria suitable for detecting and  
15 controlling impurities that may result  
16 from a change in the processing methods  
17 or that may be introduced from external  
18 sources should be employed in addition to  
19 the tests provided in the individual  
20 monograph where the presence of the  
21 impurity is inconsistent with applicable  
22 good manufacturing practices or good  
23 pharmaceutical practices.  
24 Do you see what I just read?

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1 A. Yes.  
2 Q. Did you know what I just  
3 read before I just read it to you?  
4 MS. DAVIDSON: Objection.  
5 MR. SLATER: I'm sorry,  
6 what's the objection?  
7 MS. DAVIDSON: Does he know  
8 what you read before you read it  
9 to him? I don't even understand  
10 that question.  
11 BY MR. SLATER:  
12 Q. Doctor, the information I  
13 just read to you from this official USP  
14 document, were you aware of that before I  
15 read it to you, or is this the first time  
16 you're seeing that?  
17 A. I was aware of that.  
18 Q. When they refer to a change  
19 in the processing methods, here, with the  
20 TEA and sodium nitrite quenching process  
21 and the zinc chloride process, ZHP  
22 changed the processing methods for  
23 valsartan, correct?  
24 A. Yes.

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1 Q. When they refer to  
2 impurities that may be introduced from  
3 external sources, one way that impurity  
4 can be introduced from an external source  
5 would be, for example, with the DMF in  
6 the zinc chloride process if the DMF, as  
7 purchased, contained dimethylamine as an  
8 impurity, correct?  
9 A. It could, yes.  
10 Q. And this is saying that in  
11 those circumstances, non-monograph tests  
12 and acceptance criteria should be  
13 employed in addition to the tests  
14 provided in the individual monograph  
15 where the presence of the impurity is  
16 inconsistent with applicable good  
17 manufacturing practices or good  
18 pharmaceutical practices.  
19 That's what it states,  
20 correct?  
21 A. That's what it states.  
22 Q. The presence of NDMA and  
23 NDEA in the valsartan manufactured by ZHP  
24 was unwanted, correct?

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1 A. Correct.

2 Q. In fact, when it was

3 discovered that the NDMA and NDEA were in

4 the valsartan, that resulted in a recall

5 of the finished-dose pills that had been

6 manufactured with that API, correct?

7 A. So the text you have read to

8 me relates to impurities and not unknown

9 impurities.

10 The problem with NDMA, as

11 stated by FDA, is that it's difficult to

12 detect. The methods for its detection

13 were not there. And that it was an

14 unknown below a .1 percent, where ICH

15 says you can have that impurity.

16 The method which is used for

17 effectively looking at the residual

18 solvents, as is stipulated by the USP, is

19 GC FID, that doesn't detect the NDMA.

20 So if you know what you're

21 looking for, then it is easy to go and

22 look for it. But if one doesn't know

23 what it's looking for, then it's very

24 difficult to look for an unknown impurity

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1 that you're not aware of.

2 Q. The point of this section is

3 instructing manufacturers that under

4 certain circumstances, which we just went

5 through, change in the processing methods

6 or impurities that may be introduced from

7 external sources, the manufacturer will

8 need to develop and utilize non-monograph

9 tests and acceptance criteria in order to

10 address those circumstances; that's what

11 this is saying, correct?

12 MS. DAVIDSON: Objection.

13 THE WITNESS: USP has no

14 authority to -- to dictate to

15 anyone what you have just read to

16 me.

17 BY MR. SLATER:

18 Q. That's what the words on the

19 page say, correct?

20 A. Your statement was, this

21 instruction. And my response is, USP

22 cannot instruct industry what to do.

23 However, industry followed

24 Q3A, FDA adheres to Q3A, or follows that,

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1 and ZHP followed Q3A.

2 Q. The words on the page

3 indicate that a manufacturer -- the word

4 used is "should," should employ

5 non-monograph tests and acceptance

6 criteria where there's a change in the

7 processing methods or impurities may be

8 introduced from external sources.

9 That's what the words on the

10 page say, that you're not limited just to

11 the tests and acceptance criteria listed

12 in the monograph; that's what the words

13 on the page say, correct?

14 MS. DAVIDSON: Objection.

15 THE WITNESS: So, again,

16 I'll repeat.

17 USP has no authority to say

18 what -- to say to a manufacturer

19 that you should do this. The same

20 way that I have no authority when

21 I say, Mr. Slater, please do not

22 ask yes-or-no questions, okay.

23 BY MR. SLATER:

24 Q. Did I read the language

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1 correctly?

2 A. No, no, you didn't read the

3 language incorrectly.

4 What I'm saying is that it

5 says should. That's advisory. That's

6 not binding. That's -- USP has no

7 authority to tell manufacturers what to

8 do.

9 Q3A is far more specific

10 about what should be followed and should

11 not be followed.

12 Q. A manufacturer, such as ZHP,

13 would be expected, at least as of April

14 1, 2015, to understand that it would need

15 to consider utilizing non-monograph tests

16 and acceptance criteria as opposed to

17 being limited by the USP tests and

18 acceptance criteria in the monograph;

19 that you'll agree to, that's what this

20 provided -- that's what this information

21 instructed or advised -- I'll start over,

22 actually. Because I don't want to fall

23 into the same back-and-forth with you.

24 You would agree with me that

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1 current good manufacturing practices, at  
2 least as of April 1, 2015, required the  
3 use of non-monograph tests and acceptance  
4 criteria suitable for detecting and  
5 controlling impurities that may result  
6 from a change in the processing methods  
7 or that may be introduced from external  
8 sources? That is something that  
9 manufacturers would have needed to  
10 understand, right?

11 A. As of January 2015, which is  
12 the date of this document, this document  
13 does not have any authority to stipulate  
14 to manufacturers that they need to use  
15 compendial or non-compendial tests, one.  
16 Two, this is referring to  
17 known impurities.  
18 Three, unknown impurities,  
19 unknown impurities, which by nature, by  
20 their name, are unknown, which are not  
21 expected to have an adverse -- to be --  
22 to be carcinogenic, if one does not know  
23 of the presence of such impurities and  
24 the impurity is below .1 percent, as per

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1 ICH 3A, one need not look for that.  
2 Q. Where does it say unknown  
3 impurities there? Where do you see  
4 unknown?

5 A. My point is --  
6 MS. DAVIDSON: Objection.  
7 Hold on, Dr. Afnan.  
8 I know I didn't object for,  
9 like, three questions, you got out  
10 of practice.  
11 BY MR. SLATER:  
12 Q. Where does the word  
13 "unknown" describe the impurities?  
14 A. It says, Non-monograph tests  
15 and acceptance criteria suitable for  
16 detecting and controlling impurities.  
17 If an impurity is unknown  
18 and below .1 percent concentration and  
19 not anticipated to be in a cohort of  
20 concern, then there is no requirement, as  
21 per Q3, to look for it, to isolate it, to  
22 identify it, and then to come up with  
23 non-compendial methods to detect it.  
24 Q. How would you identify NDMA

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1 in ZHP's valsartan without doing a test?  
2 MS. DAVIDSON: Objection.  
3 THE WITNESS: As per FDA and  
4 USP, USP's monograph for valsartan  
5 requires the use of GC FID. It  
6 required the use of GC FID then.  
7 It requires use of GC FID today,  
8 in 2023.  
9 FDA also stated,  
10 acknowledged, that neither  
11 industry nor regulators had the  
12 test methods suitable for  
13 detecting NDMA in valsartan. And  
14 for that reason, FDA developed  
15 those methods and published those  
16 methods.  
17 BY MR. SLATER:  
18 Q. How would one have  
19 identified NDMA in valsartan without  
20 doing a test to confirm that there was  
21 NDMA in valsartan?  
22 A. I've answered that question,  
23 and I'll answer again.  
24 The methods, which were

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1 current up through June of 2018, in  
2 industry did not actually indicate  
3 presence of NDMA. As Dr. Gottlieb  
4 stated, it's a very difficult substance  
5 to detect. It's -- the methods are not  
6 there and -- the methods are not there  
7 and, also, they -- the substance is  
8 difficult to detect. It's a residual  
9 solvent, so it needs to be taken out of  
10 solution into a gas and then tested.  
11 Q. Is there any other way to  
12 confirm whether or not there's NDMA in  
13 valsartan without running a test?  
14 It's a yes-or-no question.  
15 I just want to know, can you do it  
16 without using a test?  
17 MS. DAVIDSON: Objection.  
18 THE WITNESS: If a firm  
19 anticipated, and I'll use the word  
20 firm, FDA, if it's anticipated  
21 that had the NDMA would occur,  
22 then they would look for it.  
23 But, again, if I go to the  
24 FDA's 30th of August 2019

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1 statement, it says, Because it was  
2 not anticipated that NDMA would  
3 occur at these levels in the  
4 manufacture of the valsartan API,  
5 manufacturers would not have been  
6 testing for it. They would not  
7 have records that helped identify  
8 the issue during the -- during an  
9 inspection.  
10 So this particular risk  
11 would not have been identified on  
12 an inspection. FDA agrees that  
13 NDMA was not anticipated.  
14 BY MR. SLATER:  
15 Q. It's your opinion that as a  
16 matter of cGMP, ZHP did not have to run  
17 any tests to determine if there was NDMA  
18 or NDEA in its valsartan unless and until  
19 it anticipated that there would be NDMA  
20 or NDEA present in the valsartan?  
21 MS. DAVIDSON: Objection.  
22 THE WITNESS: Can you read  
23 the question again? Or can you  
24 repeat the question? One or the

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1 other.  
2 BY MR. SLATER:  
3 Q. Is it your opinion that ZHP  
4 did not have to test for NDMA or NDEA in  
5 its valsartan until it actually  
6 anticipated that there was NDMA or NDEA  
7 present in the valsartan?  
8 A. So as per ICH guidances, if  
9 presence of NDMA, or any other mutagenic  
10 substance, is not anticipated, then there  
11 is no test to be done for it.  
12 Q. That's your understanding of  
13 ICH?  
14 A. Yes.  
15 Q. If ZHP had determined, based  
16 on an analysis of the potential chemical  
17 reactions and the potential presence of  
18 secondary amines and nitrous acid in its  
19 valsartan manufacturing processes, under  
20 those circumstances, would GMP have  
21 required ZHP to then run a test to see if  
22 there actually was NDMA or NDEA in the  
23 valsartan?  
24 MS. DAVIDSON: Objection.

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1 THE WITNESS: So can you  
2 please repeat? I apologize,  
3 sincerely apologize to you, but  
4 can you repeat the question,  
5 please?  
6 MS. DAVIDSON: It was a long  
7 question. You don't have to  
8 apologize.  
9 BY MR. SLATER:  
10 Q. If ZHP had actually  
11 identified the potential formation of  
12 NDMA or NDEA in its valsartan  
13 manufacturing processes and knew that  
14 that was a possible impurity that could  
15 be created by those processes, under  
16 those circumstances, would GMP have  
17 required ZHP to run tests to see if there  
18 was NDMA or NDEA in the valsartan?  
19 A. Yes. But that's not the  
20 case here.  
21 Q. We know from the documents I  
22 showed you before that ZHP should have  
23 anticipated at least the potential  
24 presence of dimethylamine in the zinc

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1 chloride process, because we know that  
2 that's a known impurity of commercial  
3 DMF; we've established that, right?  
4 MS. DAVIDSON: Objection.  
5 THE WITNESS: No, we have  
6 not. I did not agree to that.  
7 BY MR. SLATER:  
8 Q. You disagree or do you have  
9 no opinion?  
10 Tell me what your opinion is  
11 on that.  
12 MS. DAVIDSON: Objection.  
13 BY MR. SLATER:  
14 Q. Let me ask the question  
15 clearly.  
16 A. Okay.  
17 Q. Are you saying that you  
18 disagree that ZHP should have been on  
19 notice of the potential for dimethylamine  
20 to be an impurity of the DMF it was  
21 purchasing? Are you saying they didn't  
22 have to be aware of that as a  
23 possibility?  
24 MS. DAVIDSON: Objection.



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1 That was a compound question  
2 again. When you say "are you  
3 saying," I think you're  
4 characterizing testimony, in which  
5 case it was mischaracterized.

6 I really think this would go  
7 more smoothly if you stuck to one  
8 question at a time.

9 MR. SLATER: We're dealing  
10 with a country lawyer who is  
11 struggling through it. I'm doing  
12 the best I can.

13 MS. DAVIDSON: From the  
14 country of New Jersey?

15 All right. Dr. Afnan, I'm  
16 sorry for the side show. Do you  
17 understand the question you're  
18 being asked right now or do you  
19 need one question repeated to you?

20 THE WITNESS: It's a very --

21 BY MR. SLATER:

22 Q. You're obviously struggling  
23 with it.

24 Let me do the best I can,

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1 because I obviously am struggling here,  
2 too. Because I can't get an answer, so  
3 it's obvious that my questions are no  
4 good.

5 Do you have an opinion, one  
6 way or the other, as to whether or not  
7 ZHP should have been aware of the  
8 potential for dimethylamine to be an  
9 impurity of the DMF it was using in the  
10 zinc chloride process? I just want to  
11 know right now if you have an opinion on  
12 that.

13 A. ZHP was not aware --

14 Q. Do you have an opinion on  
15 the question --

16 MS. DAVIDSON: Whoa. No.  
17 He was in the middle of a  
18 sentence, Adam. Come on.

19 MR. SLATER: So you're  
20 encouraging your witness not to  
21 answer with a direct answer?  
22 Okay. Thank you.

23 MS. DAVIDSON: What do you  
24 mean? He was in the middle of an

1 answer, and you stopped him and  
2 interrupted him. I don't know  
3 what his answer was going to be.

4 MR. SLATER: Counsel, all I  
5 asked was if he has an opinion on  
6 that. I didn't ask what it was.

7 MS. DAVIDSON: I understand.

8 MR. SLATER: So I'm entitled  
9 to the answer to the question.

10 MS. DAVIDSON: That does not  
11 entitle you to interrupt someone  
12 mid question -- mid answer, Adam,  
13 you know that.

14 And you wouldn't put up with  
15 that if I were to do the same.

16 MR. SLATER: Please stop  
17 talking. I'm just saying, you've  
18 talked a lot and it's taking a lot  
19 of time.

20 BY MR. SLATER:

21 Q. Just answer the question,  
22 Doctor.

23 MS. DAVIDSON: What question  
24 is pending? Because I don't know.

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1 MR. SLATER: I'm sorry you  
2 lost track, but you're not the  
3 person I'm deposing.

4 BY MR. SLATER:

5 Q. So please answer the  
6 question.

7 MS. DAVIDSON: I'm asking  
8 the court reporter to repeat the  
9 question so we know what the  
10 question is.

11 MR. SLATER: We're not going  
12 to have the court reporter repeat  
13 the question.

14 BY MR. SLATER:

15 Q. Doctor, do you, yes or no,  
16 have an opinion, I just want to know if  
17 you have an opinion, I don't want to know  
18 what it is, as to whether or not ZHP  
19 should have been aware of the potential  
20 for dimethylamine to be an impurity of  
21 the DMF it was using in the zinc chloride  
22 process; yes or no? Do you have an  
23 opinion?

24 MS. DAVIDSON: Objection.



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1 Objection. To all three questions  
2 that were just combined into one.  
3 THE WITNESS: I can't answer  
4 that. I genuinely cannot answer  
5 that.  
6 MS. DAVIDSON: We've been  
7 going a little more than an hour.  
8 So, Adam, when you're at a  
9 stopping point --  
10 MR. SLATER: I'm not there  
11 yet.  
12 MS. DAVIDSON: What do you  
13 mean?  
14 MR. SLATER: I'm not at a  
15 stopping point right now.  
16 MS. DAVIDSON: Do you have  
17 one or two questions on the same  
18 topic --  
19 MR. SLATER: I'm not going  
20 to be -- look, you can walk out of  
21 the deposition and take a break  
22 whenever you want. But I'm in the  
23 middle of a line of questioning.  
24 There's no rule in the world that

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1 says every hour we take a long  
2 break. I want to finish this line  
3 of questioning.  
4 I'm not agreeing to a break  
5 right now.  
6 MS. DAVIDSON: First of  
7 all --  
8 MR. SLATER: You know what,  
9 I don't want to talk to you,  
10 honestly, about this. I'm not  
11 ready to break. I'm in the middle  
12 of a line of questions, so it's  
13 not a good stopping time.  
14 I will now continue, unless  
15 you stop the deposition and walk  
16 out with your witness, and then  
17 I'll have to wait for you to come  
18 back.  
19 MS. DAVIDSON: So two  
20 things. Dr. Afnan, do you need a  
21 break or do you want to go a few  
22 more minutes?  
23 MR. SLATER: I'm in the  
24 middle -- there's a question that

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1 I'm in the middle of asking.  
2 You're now trying to stop me from  
3 continuing. I don't think that's  
4 kosher.  
5 Can I please finish this  
6 line of questioning? You're  
7 wasting my time. And I don't  
8 appreciate it.  
9 MS. DAVIDSON: Dr. Afnan --  
10 BY MR. SLATER:  
11 Q. Doctor, do you know whether  
12 or not ZHP knew that dimethylamine was a  
13 potential impurity of the DMF it was  
14 using in the zinc chloride process? Do  
15 you know whether they knew about that or  
16 not?  
17 MS. DAVIDSON: Objection.  
18 THE WITNESS: I do not  
19 recall, and I would need to look  
20 at the documentation to say yeah  
21 or nay.  
22 And I would like a break.  
23 BY MR. SLATER:  
24 Q. If ZHP knew --

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1 MS. DAVIDSON: Whoa. He  
2 just said he wants a break, so  
3 let's take the break and follow up  
4 afterwards.  
5 MR. SLATER: Off the record  
6 at defense counsel's insistence.  
7 VIDEO TECHNICIAN: We're off  
8 the record at 1:55 p.m.  
9 - - -  
10 (Whereupon, a brief recess  
11 was taken.)  
12 - - -  
13 VIDEO TECHNICIAN: We're  
14 back on the record at 2:07 p.m.  
15 BY MR. SLATER:  
16 Q. To be very clear, Dr. Afnan,  
17 are you relying on Dr. Xue in order to  
18 form any of your opinions?  
19 Is there anything that  
20 Dr. Xue has opined on where you would  
21 say, I'm relying on that opinion in order  
22 to form this other opinion?  
23 MS. DAVIDSON: Objection.  
24 THE WITNESS: So if I go to

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1 Statement Number 190 of my report,  
2 okay, it's regarding the July 2017  
3 e-mail, which the word "rely"  
4 is -- I refer to his statement.  
5 But, again, I have verified  
6 it by studying the -- Ms. Jucai  
7 Ge's testimony on the subject.  
8 BY MR. SLATER:  
9 Q. So this is where you  
10 referred to as detailed in the report of  
11 Fengtian Xue, an expert chemist with  
12 native fluency in Chinese, plaintiffs'  
13 experts misread this highly technical  
14 e-mail?  
15 A. Yes.  
16 Q. And am I understanding  
17 correctly that one of the reasons you're  
18 relying on Dr. Xue is because it's your  
19 understanding that he is fluent in  
20 Chinese?  
21 MS. DAVIDSON: Objection.  
22 THE WITNESS: As I said, I  
23 verified by reading Jucai Ge's  
24 testimony where she is questioned

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1 extensively about the e-mail.  
2 BY MR. SLATER:  
3 Q. So you're not relying on  
4 Dr. Xue at all?  
5 A. As I said --  
6 MS. DAVIDSON: Objection.  
7 Hold on Dr. Afnan.  
8 THE WITNESS: For me to form  
9 an opinion, okay, for me to form  
10 an opinion on the subject, I've  
11 looked at that e-mail, I've looked  
12 at Jucai Ge's statement, I've  
13 looked at -- sorry, deposition. I  
14 have looked at all of those. And  
15 I have also considered this.  
16 If you ask me which is the  
17 document that I am putting the  
18 most weight on, that's Jucai Ge's  
19 testimony -- or not testimony,  
20 deposition.  
21 BY MR. SLATER:  
22 Q. I notice that you spoke to  
23 Jucai Ge Ge, according to your report.  
24 Did I read that correctly?

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1 A. Yes.  
2 Q. What day was that?  
3 A. I don't remember. Maybe  
4 November, maybe December. It was before  
5 my report.  
6 Q. How many times did you speak  
7 to her?  
8 A. Once.  
9 Q. How long did you speak to  
10 her for?  
11 A. I do not remember.  
12 Q. Did you record the  
13 conversation?  
14 A. No.  
15 Q. Did you take notes of the  
16 conversation?  
17 A. No.  
18 Q. Do you remember what she  
19 told you?  
20 A. I remember what I asked and  
21 what she told me.  
22 Q. What was that?  
23 A. I asked about customer  
24 complaints or customer questions about

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1 unknown peaks.  
2 Q. When you say you gave the  
3 most weight to Jucai Ge's deposition,  
4 what in particular about her deposition  
5 did you put weight on with regard to your  
6 understanding of the July 27, 2017,  
7 e-mail?  
8 A. As she said in her  
9 deposition of April 2022, she had  
10 actually done -- you know, she said, I  
11 prepared for the deposition, I went back  
12 and read the e-mail, I studied the  
13 e-mail. So she had actually done  
14 background search regarding the e-mail.  
15 Q. You said you read the  
16 e-mail.  
17 Did you read the e-mail in  
18 English or in Chinese?  
19 A. English.  
20 Q. Which version?  
21 A. The version that was in the  
22 plaintiff experts' references as exhibits  
23 to plaintiff experts.  
24 Q. Did you read the testimony

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1 of Dr. Min Lee where he testified, on  
2 behalf of ZHP, has to what the e-mail  
3 said?

4 A. I do recall some of the  
5 depositions of Dr. Lee.

6 Q. Was Dr. Lee's reading of the  
7 e-mail of any significance to you in  
8 forming your opinions about that e-mail?

9 MS. DAVIDSON: Objection.

10 THE WITNESS: So Dr. Lee's  
11 deposition was -- his statements  
12 were not as detailed or as  
13 informed as Jucai Ge Ge's.

14 BY MR. SLATER:

15 Q. Did you read John Du's  
16 deposition and his testimony as to what  
17 the e-mail said?

18 A. I read that some time back.

19 Q. Was John Du's testimony as  
20 to what the e-mail said of significance  
21 to you in forming your opinions about the  
22 e-mail?

23 MS. DAVIDSON: Objection.

24 THE WITNESS: I read a lot

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1 of material to form an opinion  
2 about the e-mail and to then make  
3 a statement.

4 BY MR. SLATER:

5 Q. Was John Du's testimony in  
6 regard to what the e-mail said  
7 significant to you in forming your  
8 opinion about the e-mail?

9 MS. DAVIDSON: Objection.

10 THE WITNESS: Would it be  
11 possible for you to tell me what  
12 you mean by "significance"?

13 BY MR. SLATER:

14 Q. Something that you would say  
15 that's part of the reason why I formed my  
16 opinion is because based on what John Du  
17 said; I'm relying on what John Du said as  
18 part of the basis for my opinion.

19 A. So based on that, I'll give  
20 the answer that I've already given.

21 I looked at a lot of  
22 depositions and materials regarding the  
23 e-mail before I concluded my statement  
24 which is in my report.

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1 Q. I understand you looked at a  
2 lot of materials.

3 I'm asking if your reading  
4 of John Du's testimony, as to what the  
5 e-mail said, was significant to you in  
6 forming your opinion?

7 MS. DAVIDSON: Objection.

8 THE WITNESS: I read a lot  
9 of materials, including John Du's,  
10 to then come to a conclusion.

11 BY MR. SLATER:

12 Q. Did you read the translation  
13 of the e-mail that was provided by ZHP to  
14 us in the litigation?

15 A. I read the translation that  
16 was submitted as evidence of the  
17 plaintiff experts.

18 Q. You don't know what the  
19 e-mail said yourself, you have to rely on  
20 other people to tell you what it said,  
21 right?

22 MS. DAVIDSON: Objection.

23 BY MR. SLATER:

24 Q. You can't read the e-mail in

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1 Chinese -- new question.

2 Since you can't read the  
3 e-mail, as it was written in Chinese, you  
4 have to rely on the accuracy of  
5 translations by other people and the  
6 testimony of other people as to what it  
7 said, correct?

8 MS. DAVIDSON: Objection.

9 THE WITNESS: So I don't  
10 speak Chinese. I read it in  
11 English. I read the testimony --  
12 the deposition, not testimony, the  
13 deposition of Jucai Ge, which is  
14 quite detailed, and she provides  
15 far more information than anybody  
16 else about the e-mail.

17 I also looked at what  
18 Dr. Xue says in his testimony,  
19 which I have then referenced in my  
20 statement.

21 BY MR. SLATER:

22 Q. Since you can't read the  
23 e-mail yourself, as it was written in  
24 Chinese, you have to rely on other people

<p style="text-align: right;">Page 214</p> <p>1 to tell you what it said, correct?</p> <p>2 MS. DAVIDSON: Objection.</p> <p>3 THE WITNESS: So there is a</p> <p>4 translation. I read the</p> <p>5 translation and I looked at that</p> <p>6 translation in English.</p> <p>7 There is nobody pointing me</p> <p>8 and saying, you know what, as you</p> <p>9 read this, it means this, that or</p> <p>10 the other. And that's why I was</p> <p>11 most interested in Jucai Ge's</p> <p>12 deposition, because that's quite</p> <p>13 detailed.</p> <p>14 BY MR. SLATER:</p> <p>15 Q. Doctor, I'm honestly not</p> <p>16 sure why it is that this question is</p> <p>17 creating so much difficulty. It's</p> <p>18 literally a foundational question to move</p> <p>19 forward.</p> <p>20 You have to rely on the</p> <p>21 translation of the e-mail and the</p> <p>22 testimony of other people to understand</p> <p>23 what the e-mail said, it's not something</p> <p>24 you can read firsthand as written,</p>	<p style="text-align: right;">Page 216</p> <p>1 deposition and Dr. Xue's report; that's</p> <p>2 the basis for your understanding of what</p> <p>3 it says, correct?</p> <p>4 A. And the text of the</p> <p>5 translated text, as well as the</p> <p>6 attachment that it refers to.</p> <p>7 Q. I want to understand if you</p> <p>8 have a certain understanding of the</p> <p>9 e-mail, okay?</p> <p>10 So I'm just asking, do you</p> <p>11 understand it to say a certain thing?</p> <p>12 That's all my question is. I'm not</p> <p>13 asking for a speech. I'm not asking</p> <p>14 about anybody else on earth.</p> <p>15 I know that you're smiling</p> <p>16 and you're laughing, but I'm not asking</p> <p>17 about anything else. So please don't</p> <p>18 tell me about anything else so we can</p> <p>19 actually use my time efficiently, because</p> <p>20 I want to finish your deposition today.</p> <p>21 So please show me that</p> <p>22 respect that you'll just answer my</p> <p>23 question.</p> <p>24 MS. DAVIDSON: I'm going to</p>
<p style="text-align: right;">Page 215</p> <p>1 because you don't read Chinese, correct?</p> <p>2 MS. DAVIDSON: Objection.</p> <p>3 THE WITNESS: I do not read</p> <p>4 Chinese. And, again, as Jucai Ge</p> <p>5 says, the e-mail is confusing, it</p> <p>6 badly written, and she is reading</p> <p>7 it in Chinese.</p> <p>8 So, no, I'm not reading</p> <p>9 Chinese. I'm reading the</p> <p>10 translation that was provided in</p> <p>11 the plaintiff experts -- by the</p> <p>12 plaintiff experts.</p> <p>13 BY MR. SLATER:</p> <p>14 Q. Your only basis to say the</p> <p>15 e-mail is confusing and badly written is</p> <p>16 Jucai Ge saying that in testimony, right?</p> <p>17 You have to rely on her for that, right?</p> <p>18 A. She says that, Dr. Xue says</p> <p>19 that. Jucai Ge talked to Dr. Lin, who</p> <p>20 was the author, and the author says, no,</p> <p>21 that's not what I said.</p> <p>22 Q. If I understand correctly,</p> <p>23 your understanding of what the e-mail</p> <p>24 says really comes from Jucai Ge's</p>	<p style="text-align: right;">Page 217</p> <p>1 object to that colloquy. I'm</p> <p>2 objecting to that colloquy.</p> <p>3 You're badgering.</p> <p>4 MR. SLATER: You can object.</p> <p>5 I'm going to continue.</p> <p>6 MS. DAVIDSON: You're</p> <p>7 interrupting me. Please do not</p> <p>8 badger the witness. Please do not</p> <p>9 speak to the witness that way.</p> <p>10 You're asking the witness to show</p> <p>11 you respect, so show respect to</p> <p>12 the witness.</p> <p>13 Thank you.</p> <p>14 MR. SLATER: Thank you very</p> <p>15 much for those instructions. I</p> <p>16 appreciate it.</p> <p>17 BY MR. SLATER:</p> <p>18 Q. Does your -- rephrase.</p> <p>19 Do you understand the e-mail</p> <p>20 to say, in part, that there is NDMA in</p> <p>21 valsartan; yes or no?</p> <p>22 A. The e-mail, based on the</p> <p>23 translation that I have seen, as well as</p> <p>24 the patent which was accompanied with it,</p>

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1 alone without anything else, does not  
2 tell me there is NDMA in valsartan.

3 I have supporting evidence  
4 from Jucai Ge and Dr. Xue, and others,  
5 that effectively says that's not the  
6 statement that the e-mail is making.

7 Q. Who are the others?

8 A. There are others who have  
9 been deposed.

10 Q. Who else said that it  
11 doesn't say that there's NDMA in  
12 valsartan?

13 A. The two -- the two others  
14 that I cannot recall right now that you  
15 mentioned.

16 Q. You think that Min Lee and  
17 John Du said that the e-mail does not  
18 indicate that there's NDMA in valsartan?  
19 You think that's their testimony under  
20 oath?

21 MS. DAVIDSON: Objection.

22 THE WITNESS: Yes.

23 BY MR. SLATER:

24 Q. Is it your understanding

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1 that the e-mail indicates that the NDMA  
2 in the valsartan was caused by the  
3 quenching with sodium nitrite?

4 MS. DAVIDSON: Objection.

5 THE WITNESS: The e-mail is  
6 talking about Impurity K, it's not  
7 talking about NDMA. It's taking  
8 about irbesartan process. And  
9 it's talking about, specifically,  
10 formation of a nitroso compound  
11 which looks like a nitroso  
12 valsartan. There is a chemical  
13 formula given in that e-mail which  
14 is different from that of  
15 valsartan.

16 BY MR. SLATER:

17 Q. Are you aware of the  
18 language where it says that the NDMA is  
19 produced by the quenching of the  
20 valsartan with sodium nitrite? Are you  
21 aware that the e-mail says that, or do  
22 you dispute that the e-mail says that?

23 MS. DAVIDSON: Objection.

24 Are you referring to a specific

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1 translation of the e-mail? Are  
2 you referring to the e-mail?

3 MR. SLATER: I'm referring  
4 to the e-mail.

5 MS. DAVIDSON: The e-mail in  
6 Chinese?

7 MR. SLATER: Counsel, I'm  
8 not going to go back-and-forth  
9 with you. Just -- you objected to  
10 the form of the question. Please  
11 answer.

12 I'm done with these  
13 discussions with you. I have  
14 three more hours on the record.  
15 I'm not going to spend it talking  
16 to you.

17 BY MR. SLATER:

18 Q. Please answer the question,  
19 Doctor.

20 A. Can I please get the e-mail  
21 on the screen?

22 Q. Sure. One second.

23 A. Thank you.

24 Q. I'm going to get you the

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1 e-mail, Doctor.

2 A. Thank you.

3 And if -- Mr. Slater, if I  
4 smile, I am not disrespecting you.

5 Q. I don't mind smiling.  
6 Smiling is great. It's a healthy thing  
7 to do. It's good for endorphins.

8 MR. SLATER: I think we're  
9 up to Exhibit-9 now, right?

10 - - -

11 (Whereupon, Exhibit Afnan-9,  
12 ZHP00190573-0574, Notice on the  
13 Results of the Report of the  
14 Preliminary Investigation on the  
15 Formation of Unknown Impurities  
16 Resulting from the Sodium Azide  
17 Quenching in Crude Irbesartan, was  
18 marked for identification.)

19 - - -

20 BY MR. SLATER:

21 Q. So on the screen is  
22 Exhibit-9.

23 A. Yes.

24 Q. That's the e-mail



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1 translation that you saw?  
2 A. That is the e-mail  
3 translation that I saw.  
4 Q. Let's go to the second page,  
5 please.  
6 Do you see at the very top  
7 of the second page of the e-mail there's  
8 some language up above some chemistry  
9 formulas? Do you see that?  
10 A. Yes.  
11 Q. And they're talking in the  
12 first sentence about something that they  
13 saw in irbesartan that they're working on  
14 a manufacturing process for, they're  
15 experimenting with a manufacturing  
16 process, and they're talking about  
17 irbesartan, right?  
18 A. Yes.  
19 Q. And it says, Through the  
20 secondary mass spectrometry analysis, it  
21 can be inferred that the extra NO  
22 substituent is in the cyclic compound  
23 fragment and it is very likely that it is  
24 an N-NO compound.

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1 I'm going to stop there.  
2 They're talking about what  
3 they're seeing in the irbesartan, right?  
4 MS. DAVIDSON: Objection.  
5 THE WITNESS: Can I go to  
6 Page 1 of this e-mail, please?  
7 BY MR. SLATER:  
8 Q. Sure. Do you need us to do  
9 that for you?  
10 MR. SLATER: Go ahead.  
11 We'll put on Page 1, let's go.  
12 THE WITNESS: I have it  
13 open.  
14 According to the results of  
15 our telephone conversation with  
16 the technology department of  
17 Chuannan Plant 1 today, due to the  
18 incomplete quenching of sodium  
19 azide caused by the separate  
20 treatment of irbesartan sodium  
21 azide wastewater, there is a  
22 frequent occurrence of muffled  
23 explosion in the production  
24 process. So the technology

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1 department carried out the  
2 technical improvement by which the  
3 sodium azide quenching takes place  
4 in the unstratified step in the  
5 crude irbesartan process.  
6 However, after the  
7 improvement, there is an unknown  
8 impurity of about .544 percent at  
9 26 minutes in the crude  
10 irbesartan, and it is the largest  
11 impurity in the irbesartan crude  
12 product. We investigated, at 26  
13 minutes, unknown impurity that  
14 occurred in the crude irbesartan  
15 after the improvement -- thank  
16 you -- of the sodium azide  
17 quenching process sent by the  
18 technology department.  
19 Based on the results of  
20 these two days, currently it can  
21 be confirmed that the impurity is  
22 a nitroso derivative of irbesartan  
23 and its precise molecular weight  
24 of 458.2306, and the signal peak

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1 of M plus K plus 496.1865 can also  
2 be observed. The matching  
3 molecular formula is C<sub>25</sub>H<sub>27</sub>N<sub>7</sub>O<sub>2</sub>.  
4 Compared with the molecular  
5 formula of irbesartan, it has an  
6 extra NO but missing one hydrogen  
7 atom. The estimated possible  
8 structural formula is shown as  
9 follows.  
10 Okay. Now, he attached to  
11 this e-mail, in Chinese, the  
12 patent. And the patent talks  
13 about Impurity K, Impurity K being  
14 present in that process, not in --  
15 not a nitrosamine in valsartan.  
16 So I've gone through this  
17 e-mail several times. And, again,  
18 this is where Jucai Ge's testimony  
19 or -- deposition, not testimony,  
20 becomes very helpful.  
21 BY MR. SLATER:  
22 Q. Great. All I asked you is  
23 if that first part of the sentence at the  
24 top was referring to irbesartan up to the

<p style="text-align: right;">Page 226</p> <p>1 semi-colon.</p> <p>2 Do you agree that's talking</p> <p>3 about what they saw in the irbesartan?</p> <p>4 MS. DAVIDSON: Objection.</p> <p>5 THE WITNESS: So I would</p> <p>6 have to guess. I -- my assumption</p> <p>7 is that the whole e-mail is about</p> <p>8 irbesartan, from beginning to the</p> <p>9 end.</p> <p>10 BY MR. SLATER:</p> <p>11 Q. The first sentence at the</p> <p>12 top of Page 2 says, Through the secondary</p> <p>13 mass spectrometry analysis, it can be</p> <p>14 inferred that the extra NO substituent is</p> <p>15 in the cyclic compound fragment and it is</p> <p>16 very likely that it is an N-NO compound.</p> <p>17 Do you see what I just read?</p> <p>18 A. Yes.</p> <p>19 Q. And you just confirmed your</p> <p>20 understanding is that has to do with what</p> <p>21 they were seeing in irbesartan, right?</p> <p>22 MS. DAVIDSON: Objection.</p> <p>23 THE WITNESS: I did not.</p> <p>24 BY MR. SLATER:</p>	<p style="text-align: right;">Page 228</p> <p>1 You know that for a fact,</p> <p>2 correct?</p> <p>3 MS. DAVIDSON: Objection.</p> <p>4 THE WITNESS: I do not.</p> <p>5 Again, going back to Jucai Ge, Dr.</p> <p>6 Lin was situated -- was physically</p> <p>7 placed at a different site,</p> <p>8 different location. He was</p> <p>9 looking -- he was a development</p> <p>10 department -- you know, technology</p> <p>11 department. He was looking at a</p> <p>12 manufacturing process for</p> <p>13 irbesartan.</p> <p>14 And, actually, specifically</p> <p>15 looking at the effluent coming</p> <p>16 from the process and looking at</p> <p>17 what could be formed and what</p> <p>18 could not be formed.</p> <p>19 So as he's doing this and he</p> <p>20 goes on to say that, you know,</p> <p>21 find the patent, which he had</p> <p>22 researched and, effectively, this</p> <p>23 is a hypothetical e-mail, because</p> <p>24 he's responding to the patent.</p>
<p style="text-align: right;">Page 227</p> <p>1 Q. You literally just said the</p> <p>2 entire e-mail is about irbesartan.</p> <p>3 Wouldn't that sentence be</p> <p>4 included?</p> <p>5 A. Well, that is -- again, we</p> <p>6 go back to, you know what, it's the</p> <p>7 translation of the e-mail, so on and so</p> <p>8 forth.</p> <p>9 Potentially, yes, it's</p> <p>10 referring to irbesartan. Okay.</p> <p>11 Q. Now, after the semi-colon</p> <p>12 Dr. Lin says, It is similar to the</p> <p>13 N-nitroso dimethylamine that occurs in</p> <p>14 valsartan when quenched with sodium</p> <p>15 nitrite.</p> <p>16 Do you see what I just read?</p> <p>17 A. Yes.</p> <p>18 Q. Forgetting about the e-mail</p> <p>19 for a second, as a matter of fact in the</p> <p>20 world, as of July 2017, there was NDMA in</p> <p>21 valsartan and it was occurring when the</p> <p>22 valsartan was quenched with sodium</p> <p>23 nitrate. That's when the NDMA was</p> <p>24 forming.</p>	<p style="text-align: right;">Page 229</p> <p>1 And the patent talks about</p> <p>2 Impurity K, which is a nitroso</p> <p>3 valsartan compound.</p> <p>4 BY MR. SLATER:</p> <p>5 Q. I'm not asking about the</p> <p>6 e-mail right now, this question, okay.</p> <p>7 Was there NDMA in the</p> <p>8 valsartan manufactured with the zinc</p> <p>9 chloride process?</p> <p>10 A. That was discovered in June</p> <p>11 2018.</p> <p>12 Q. So the answer is yes, right?</p> <p>13 A. In June 2018, ZHP identified</p> <p>14 NDMA in valsartan.</p> <p>15 Q. The NDMA was formed at the</p> <p>16 point when the sodium azide was quenched</p> <p>17 with sodium nitrite; that's when the NDMA</p> <p>18 formed, correct?</p> <p>19 A. According to FDA analysis,</p> <p>20 NDMA was present in the -- NDMA was</p> <p>21 present in their second process where</p> <p>22 sodium nitrite was formed. It was -- and</p> <p>23 then into the zinc chloride process.</p> <p>24 That was discovered in June 2018.</p>

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1 Q. I'm sorry, Doctor, I have to  
2 ask again, because I have no idea what  
3 you just said. I just didn't understand  
4 it.

5 Doctor, the NDMA formed in  
6 the zinc chloride process was formed when  
7 the sodium azide was quenched with sodium  
8 nitrite; that's when the formation  
9 occurred, correct?

10 MS. DAVIDSON: Objection.

11 THE WITNESS: So as of yet,  
12 there is no statement by FDA which  
13 says it formed then. The  
14 investigation -- deviation  
15 investigation, which we were  
16 discussing earlier, specifically  
17 is looking at multiple pathways of  
18 formation of NDMA.

19 BY MR. SLATER:

20 Q. Do you have an opinion as to  
21 when the NDMA formed during the zinc  
22 chloride process? Was it during the  
23 quenching with sodium nitrite or during  
24 another part of the process, or do you

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1 have no opinion?

2 MS. DAVIDSON: Objection.

3 THE WITNESS: That I would  
4 have to defer to a synthetic  
5 organic chemist. I would suggest  
6 Dr. Xue.

7 BY MR. SLATER:

8 Q. I would like you to assume  
9 that this e-mail says that what they were  
10 seeing in the irbesartan was similar to  
11 the NDMA that occurs in valsartan when  
12 quenched with sodium nitrite. I'd like  
13 you to assume that that's what the e-mail  
14 says, okay?

15 Do you understand that I'm  
16 asking you to assume that?

17 A. So you want me to go into  
18 hypothetical, okay.

19 Q. I do. You may not know  
20 this, but we're allowed to ask  
21 hypothetical questions of expert  
22 witnesses.

23 A. I appreciate that.

24 Q. And I'd also like you to

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1 assume that there was NDMA in valsartan  
2 manufactured with the zinc chloride  
3 process and it occurred and formed when  
4 the sodium azide was quenched with sodium  
5 nitrite. I'd also like you to assume  
6 that, okay?

7 A. Okay.

8 Q. Would that change your  
9 opinion as to when ZHP was aware there  
10 was NDMA in its valsartan and how it  
11 formed in July of 2017?

12 MS. DAVIDSON: Objection.

13 THE WITNESS: You have two  
14 assumptions and then you would  
15 like me to assume a third, based  
16 on your two assumptions.

17 So, again, I would like to  
18 go back to what FDA says, what my  
19 testimony said, my report states  
20 is that neither the FDA nor  
21 industry knew how NDMA was formed,  
22 neither FDA nor industry had  
23 methods to test for them.

24 And so, therefore, if they

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1 didn't know how to test for it and  
2 if they didn't know it was there,  
3 then the question is that -- the  
4 engagement between you and I is  
5 purely theoretical, and not even  
6 theoretical, it's hypothetical.

7 So, you know, at the time of  
8 2017, ZHP did not know that NDMA  
9 was present in its valsartan.

10 BY MR. SLATER:

11 Q. Can you answer my question,  
12 please?

13 MS. DAVIDSON: Objection.

14 THE WITNESS: Please ask it  
15 again.

16 Hypothetical 1 was what,  
17 that there is --

18 BY MR. SLATER:

19 Q. I'll ask the question  
20 differently for you.

21 A. Thank you.

22 Q. I already have your one  
23 answer, so we have that for the record in  
24 the transcript as your sworn testimony.

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1 Now I'll ask a different  
2 question in a different way.  
3 If the e-mail says that  
4 there was NDMA in valsartan and it occurs  
5 when it's quenched with sodium nitrite,  
6 that would be an accurate statement,  
7 correct?

8 MS. DAVIDSON: Objection.

9 THE WITNESS: If the e-mail  
10 said NDMA was present, yes, but  
11 the e-mail does not say that.

12 BY MR. SLATER:

13 Q. And if that was a correct  
14 statement -- well, rephrase.

15 And if the e-mail says that  
16 there was NDMA in valsartan and it  
17 occurred when the valsartan was quenched  
18 with sodium nitrite, not only would that  
19 be a true statement, but it would also  
20 prove that at least some people in ZHP  
21 were aware of the presence of the NDMA  
22 and how it was forming, right?

23 MS. DAVIDSON: Objection.

24 THE WITNESS: ZHP did not

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1 know -- again, you know, ZHP did  
2 not know.

3 Dr. Lin says that's not what  
4 he said in the e-mail. Jucai Ge  
5 says that's not what it says in  
6 the e-mail. So, you know, it's  
7 purely hypothetical to go down  
8 this path that if this happened  
9 and that happened, then this other  
10 thing would have happened.

11 As your statements, your  
12 conclusion, based on your  
13 theoretical statements, are  
14 connected. But that's not the  
15 case here. I really need to make  
16 sure my testimony is accurate, as  
17 accurate as it can be.

18 BY MR. SLATER:

19 Q. If ZHP knew that there was  
20 NDMA in valsartan and knew that it was  
21 forming during the quenching of the  
22 valsartan during the manufacturing  
23 process with sodium nitrite, if they knew  
24 that, good manufacturing practices

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1 required them to immediately notify their  
2 customers and the FDA and cease  
3 manufacture with that process until they  
4 got further guidance, correct?

5 MS. DAVIDSON: Objection.

6 THE WITNESS: ZHP did  
7 exactly that in June 2018.

8 BY MR. SLATER:

9 Q. And if they knew that in  
10 July of 2017, they would have been  
11 required to do it in July of 2017 and not  
12 wait until June of 2018, right?

13 A. Whenever they would have  
14 become aware of it, they would have had  
15 to act. But that was not the case, they  
16 did not know in June 2017.

17 Q. Well, you actually don't  
18 know when they knew; you're just deciding  
19 which witnesses to believe and which  
20 translations of the document to believe,  
21 but you don't know at all what happened,  
22 right?

23 MS. DAVIDSON: Objection.

24 THE WITNESS: Respectfully,

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1 incorrect. I -- you know, seven  
2 years at FDA told me to look for  
3 evidence, look for evidence, look  
4 for evidence.

5 The evidence is there when  
6 they received an e-mail, or a  
7 communication, from Novartis  
8 saying, what is that peak which is  
9 there, send us data. They did  
10 send data. They sent GC FID data.  
11 They also sent GCMS data which was  
12 not alluding, you know, the  
13 unknown peak.

14 BY MR. SLATER:

15 Q. Did you -- I'm sorry, I  
16 didn't realize you were still talking.  
17 Go ahead.

18 A. So Novartis actually told  
19 them that the chances are that using your  
20 method, it will dilute at a different  
21 time than ours. FDA didn't know either.

22 So FDA, who had reviewed the  
23 ANDAs related to this API, would have  
24 known, would have actually assessed

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1 whether NDMA would have been formed or  
2 not.  
3 So ZHP didn't know until  
4 June 2018.  
5 Q. You just mentioned the FDA  
6 review of the ANDAs.  
7 You just referred to that,  
8 right?  
9 A. Yes.  
10 Q. When the FDA did whatever  
11 review it did of the ANDAs that were  
12 filed, is it your testimony that the FDA  
13 would, at that point, have done a  
14 cGMP-compliant risk assessment of the  
15 entire manufacturing process?  
16 MS. DAVIDSON: Objection.  
17 THE WITNESS: So there are  
18 parallel activities for an  
19 approval process going on. One  
20 activity is what's going on at the  
21 API facility. And that API  
22 facility was also inspected in, I  
23 think, 2011 and then in 2016 by  
24 EDQM, who accepted the facility

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1 and gave them a GMP certificate.  
2 FDA had the DMF, which --  
3 which the process, there's a  
4 chlorine process had been filed  
5 through as an amendment. That was  
6 also there.  
7 The ANDA process would have  
8 looked at, effectively, the tests  
9 for the API. It would have looked  
10 for the process of making the drug  
11 substance, and -- the process, as  
12 well as the release criteria for  
13 the raw substance. And they would  
14 have looked at whether the  
15 chemistry recorded in the sections  
16 of the Model 3 would be accurate,  
17 correct or not.  
18 And that would have then  
19 been verified through either a GMP  
20 inspection or a PAI inspection.  
21 BY MR. SLATER:  
22 Q. Could you answer my  
23 question, please?  
24 MS. DAVIDSON: Objection.

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1 BY MR. SLATER:  
2 Q. Or I can ask it again.  
3 Do you want me to ask you  
4 again, Doctor?  
5 Because I don't really  
6 understand what you just said. So I'm  
7 going to try to ask a question that's  
8 specific and hope that I can get a  
9 specific answer. That's my hope.  
10 When the FDA reviewed the  
11 ANDAs that were submitted with regard --  
12 which then incorporated, by reference,  
13 the DMFs for the TEA with sodium nitrite  
14 quenching and the zinc chloride  
15 processes, did the FDA perform a  
16 cGMP-compliant risk assessment of each of  
17 those manufacturing processes?  
18 A. I did respond.  
19 Q. It's a yes-or-no question.  
20 Can you just tell me if the  
21 review by the FDA is to the level of a  
22 cGMP-compliant risk assessment?  
23 A. With all due respect, sir,  
24 your question is wrong.

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1 They review an ANDA  
2 application. It's not a GMP activity.  
3 It's managed through other sections of  
4 the CFR. So FDA would have looked at the  
5 sections of the common technical dossier  
6 that would have been provided. They  
7 would have also looked at the GMP status  
8 of the facility for approval of the ANDA.  
9 Q. Looking at the e-mail of  
10 July 27, 2017, the second paragraph after  
11 the chemistry diagrams says, If it is  
12 confirmed as the above-specified  
13 structure, then its toxicity will be very  
14 strong and there will be an extremely  
15 high GMP risk. This is a common problem  
16 in the production and synthesis of sartan  
17 APIs. It is recommended to improve other  
18 quenching processes (such as NACIO) along  
19 with the optimization of the valsartan  
20 sodium azide quenching process.  
21 Do you see that?  
22 A. I see that.  
23 Q. So, first of all, where he  
24 says, This is a common problem with the



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1 production and synthesis of sartan APIs,  
2 you understand that ZHP manufactured  
3 other sartans, including irbesartan?

4 A. Yes.

5 Q. If ZHP was aware that the  
6 quenching with sodium nitrite causing  
7 nitrosamines was a common problem in the  
8 production and synthesis of sartan APIs,  
9 they would have been duty bound to notify  
10 the FDA and their customers with regard  
11 to all of their sartans, correct?

12 If that's what they knew,  
13 they would have been required to notify  
14 the FDA and their customers, right?

15 A. As the e-mail says, it says  
16 if it is confirmed. And by the way,  
17 that's NACLO, sodium hydrochloride.

18 So it says, If it is  
19 confirmed as the above speculated  
20 structure, then its toxicity will be  
21 strong. Okay.

22 Q. He then says, It is  
23 recommended to improve other quenching  
24 processes along with the optimization of

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1 the valsartan sodium azide quenching  
2 process.

3 If that's correct, that he  
4 was recommending, based on everything he  
5 talked about, optimizing the valsartan  
6 sodium azide quenching process, based on  
7 having stated above that the NDMA was  
8 formed during the sodium nitrite  
9 quenching of the sodium azide, that would  
10 be something that ZHP would have been  
11 required to notify the FDA and their  
12 customers of immediately, right?

13 A. If that was the case, they  
14 would have had to inform FDA and  
15 customers immediately. That was not the  
16 case.

17 If I may be allowed to read  
18 the next line of the next paragraph. I  
19 have also attached a patent of a 2013  
20 sodium azide sodium hyperchloride  
21 quenching method by Zhejiang Second  
22 Pharma Company Limited. They proposed  
23 that the use of sodium azide quenching  
24 will result in the formation of N-NO

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1 impurities.

2 Which, actually, as per the  
3 attached, is a -- is a nitroso valsartan.  
4 You know, the nitroso compounds are many  
5 and plenty. And, therefore, that  
6 compound that he's referring to, if you  
7 look at the patent, is actually Impurity  
8 K.

9 Q. Do you see where this says,  
10 At the same time they -- meaning this  
11 other company, Zhejiang Second Pharma  
12 Company -- used ZHP's crude valsartan in  
13 their LC-MS test and detected this  
14 impurity.

15 And the impurity that was  
16 referred to above in the valsartan was  
17 NDMA, correct?

18 A. Hold on. I lost you. Okay.  
19 Allow me.

20 So, okay. What was your  
21 question, please?

22 Q. This states that this other  
23 pharmaceutical company used ZHP's crude  
24 valsartan in their LC-MS test and

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1 detected this impurity.

2 The impurity that was  
3 identified up above in the valsartan was  
4 listed as NDMA, correct?

5 A. Can you point me to where it  
6 says this is NDMA?

7 Q. Sure.

8 MR. SLATER: Scroll to the  
9 top, please.

10 THE WITNESS: Okay. This is  
11 similar, similar, to  
12 N-nitrosamines. This is similar.

13 BY MR. SLATER:

14 Q. You don't have to read the  
15 rest of the sentence, Doctor. With all  
16 due respect, it says that what they saw  
17 in the irbesartan was similar to the NDMA  
18 that occurs in valsartan when quenched  
19 with sodium nitrite.

20 That's what the document  
21 says, right?

22 MS. DAVIDSON: Objection.

23 That's what the translation says.

24 THE WITNESS: Which, again,

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1 if I follow what I said earlier,  
2 if I look at both Professor Xue  
3 and if I look at Jucai Ge, who  
4 spoke to Dr. Lin in detail and  
5 asked the questions, Dr. Lin says,  
6 I never made that statement. That  
7 was not my intent.

8 So as we go through to the  
9 second question, or the last  
10 paragraph, yes, the statement  
11 which says, At the same time they  
12 used ZHP's crude valsartan.

13 So this e-mail was about  
14 Impurity K. This is about  
15 Impurity K, which is a nitroso  
16 valsartan. It's a valsartan  
17 molecule with an N-O attached to  
18 it.

19 BY MR. SLATER:

20 Q. Now you think the whole  
21 e-mail is about Impurity K? It's not  
22 about irbesartan anymore?

23 MS. DAVIDSON: Objection.

24 BY MR. SLATER:

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1 Q. I'm just asking.

2 Before you said the whole  
3 e-mail was about irbesartan, now it's  
4 about Impurity K?

5 MS. DAVIDSON: Wait a  
6 minute. That's really  
7 mischaracterizing his testimony  
8 and --

9 MR. SLATER: Without you  
10 giving him what to say. You  
11 objected. He can answer.

12 MS. DAVIDSON: I'm not  
13 telling --

14 MR. SLATER: He doesn't need  
15 to take signal from you. The last  
16 one he followed your objection and  
17 followed it and said exactly what  
18 you said. Let's try not to do  
19 that, please.

20 MS. DAVIDSON: That is  
21 literally the pot calling --

22 MR. SLATER: I don't want to  
23 argue with you. I really don't.

24 MS. DAVIDSON: I understand,

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1 Adam. But you're arguing with the  
2 witness. And my job today is to  
3 make sure that this deposition  
4 proceeds in an appropriate manner.

5 The way you're talking to  
6 the witness is rude. So I'm just  
7 asking you not to.

8 MR. SLATER: I don't think  
9 I'm being rude at all. There's an  
10 audiotape of this transcript -- of  
11 this deposition, the video has an  
12 audio. So anybody that needs to  
13 look at it, I stand behind  
14 everything I've done today.

15 I have one of the most  
16 nonresponsive witnesses I've ever  
17 deposed in my life. I feel like  
18 the deposition has been obstructed  
19 to a great extent, and I'm doing  
20 the best I can.

21 I'm not raising my voice.  
22 And I'm not yelling. And I think  
23 that my request to not lead the  
24 witness with speaking objections

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1 is reasonable.

2 MS. DAVIDSON: I did not  
3 lead the witness in any way, and  
4 you know that. I was asking you  
5 to please be polite, not badger  
6 him, and just simply ask questions  
7 and answers, which would make the  
8 deposition go more quickly.

9 You're concerned about  
10 eating up time, but you're eating  
11 up time berating the witness.

12 BY MR. SLATER:

13 Q. Show me where it says  
14 Impurity K in the e-mail. I just -- I  
15 might have missed that.

16 A. Impurity K is in the patent,  
17 which was attached to the e-mail.

18 MR. SLATER: We can take  
19 that down.

20 I just need to know if you  
21 guys are going to say you need a  
22 break again, because I'm going to  
23 go into something else.

24 If you need a break, you can

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1 do it now. Otherwise I'd like to  
2 start and not stop in three  
3 minutes.

4 MS. DAVIDSON: I've been  
5 trying to take a break about every  
6 hour, and I believe we came back  
7 at 2:05. So I was not going to  
8 ask for another break for 15  
9 minutes.

10 Unless Dr. Afnan needs one  
11 now. He's the one who should be  
12 the guide of it.

13 THE WITNESS: Let's go for  
14 another ten minutes, please.

15 MR. SLATER: I'm just  
16 putting up the next exhibit.

17 - - -

18 (Whereupon, Exhibit  
19 Afnan-10, No Bates, FDA Statement  
20 on the FDA's Ongoing Investigation  
21 Into Valsartan and ARB Class  
22 Impurities and the Agency's Steps  
23 to Address the Root Causes of the  
24 Safety Issues, was marked for

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1 identification.)

2 - - -

3 BY MR. SLATER:

4 Q. On the screen is what we  
5 have marked as Exhibit -- I think  
6 we're -- on the screen is Exhibit-10,  
7 which is an FDA statement dated January  
8 25, 2019.

9 Do you see that?

10 A. Yes.

11 Q. Is this something you relied  
12 on in forming your opinions in this case?

13 A. It is quoted in my -- in my  
14 testimony, so yes.

15 MR. SLATER: Let's go to the  
16 second page, third paragraph.  
17 Blow it up a little bit.

18 I'm just going to go -- the  
19 paragraph that starts, Since then.  
20 There we go.

21 BY MR. SLATER:

22 Q. I'm looking at the -- let me  
23 restart.

24 Looking now at the second

1 page of this e-mail -- rephrase.

2 Looking now at the second  
3 page of this statement, there's a  
4 paragraph that starts, Since then, the  
5 FDA and additional manufacturers of other  
6 ARB medicines have identified more cases  
7 of NDMA impurities as well as NDEA  
8 impurities.

9 Do you see that?

10 A. Yes.

11 Q. Looking now at the paragraph  
12 that starts with, Since then, the second  
13 sentence says, We've placed a ZHP  
14 facility on import alert to stop all of  
15 its API and finished drugs made using  
16 ZHP's API from legally entering the  
17 United States. We also issued them a  
18 warning letter outlining several  
19 manufacturing violations, including  
20 impurity control, change control and  
21 cross-contamination from one  
22 manufacturing process line to another.

23 Do you see what I just read?

24 A. Yes.

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1 Q. So in this FDA statement  
2 that you relied on, the FDA makes clear  
3 that they issued a warning letter to ZHP,  
4 correct?

5 A. Correct.

6 Q. They made clear that the  
7 warning letter outlined several  
8 manufacturing violations, correct?

9 MS. DAVIDSON: Objection.

10 BY MR. SLATER:

11 Q. Correct?

12 A. That's what the warning  
13 letter says.

14 Q. And those violations are  
15 cGMP violations identified in the warning  
16 letter, correct?

17 A. Okay. Yes.

18 Q. They then list, in general  
19 fashion, the nature of those cGMP  
20 manufacturing violations as including  
21 impurity control, change control and  
22 cross-contamination from one  
23 manufacturing process line to another.

24 That's what it says, right?

1 A. Yes.  
2 Q. So in this statement that  
3 you relied on, the FDA made clear, in  
4 January of 2019, that they issued an  
5 import alert against ZHP and issued them  
6 a warning letter identifying several  
7 manufacturing violations of cGMP.  
8 That's in the letter, right?  
9 That's in the statement, right?  
10 MS. DAVIDSON: Objection.  
11 BY MR. SLATER:  
12 Q. Correct?  
13 A. That's what the letter says.  
14 Q. If you go to the last  
15 sentence of this paragraph, it says,  
16 Nonetheless, our inspections did reveal  
17 systemic problems of supervision that  
18 could have created the conditions for  
19 quality issues to arise.  
20 That's what the letter  
21 says -- that's what the statement says,  
22 again, with regard to their inspections  
23 of ZHP, correct?  
24 A. That's what it says in the

1 letter, yes.  
2 MR. SLATER: We can take  
3 that one down.  
4 BY MR. SLATER:  
5 Q. With regard to the import of  
6 the warning letter, the warning letter is  
7 a serious document, correct?  
8 MS. DAVIDSON: Objection.  
9 THE WITNESS: The warning  
10 letter is informal and advisory.  
11 That's what the FDA says. FDA  
12 doesn't consider warning letters  
13 as final agency action. That's  
14 what the FDA says.  
15 BY MR. SLATER:  
16 Q. The warning letters are  
17 issued only for violations of regulatory  
18 significance; that's the position of the  
19 FDA, right?  
20 A. There is a sequence to the  
21 issuance of warning letters. The  
22 sequence is that there is an inspection,  
23 there is a response from the firm, then a  
24 warning letter is issued if there is

1 grounds to do this.  
2 Now, in this particular  
3 case, FDA is doing several things.  
4 Number one, FDA is  
5 effectively holding ZHP on the hook to  
6 complete its investigation. Their  
7 warning letter is issued in November of  
8 2018. The inspection was from 27th of  
9 July to 3rd of August. They -- ZHP  
10 informed FDA, in June, of presence of  
11 NDMA and at the same time informed FDA  
12 that it had stopped manufacture of  
13 valsartan, it had stopped shipping  
14 valsartan and it had informed its clients  
15 to stop using the API. They have done it  
16 twice.  
17 So, effectively, the warning  
18 letter is coming pretty late in the day.  
19 And that's because FDA is still waiting  
20 for the investigation to complete and for  
21 ZHP to give the information to them.  
22 When -- the evidence of this  
23 is, when ZHP responded, ZHP gave an  
24 immediate response and then gave a

1 detailed response, FDA came back with  
2 some additional questions and very  
3 friendly tone asking for, can you speed  
4 up some of the questions?  
5 So the warning letter is not  
6 a, you know, this is the end of the day.  
7 The warning letter is to engage in a  
8 dialogue with the agency to get to the  
9 root cause of the issue. That's why  
10 warning letters are issued.  
11 And, again, the warning  
12 letter, according to the regulatory  
13 operations manual, is not -- is informal  
14 and advisory, and it's not considered  
15 warning letters -- you know, they aren't  
16 considered to be final agency action.  
17 Q. The FDA never, ever came out  
18 and said that the violations identified  
19 in the warning letter did not exist and  
20 did not occur? The FDA never said that,  
21 right?  
22 A. Well, FDA closed the warning  
23 letter sometime later, which means it  
24 accepted it.



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1 ZHP had already challenged  
2 some of the observations, and ZHP  
3 continued to engage the FDA in its  
4 response to the warning letter, addressed  
5 those issues.

6 Q. What the FDA did is, they  
7 said, now that we've identified these  
8 serious systemic problems and we've given  
9 you the warning letter, fix them; here is  
10 the violations and now you have to fix it  
11 and we're reserving the right to take  
12 final enforcement action if we want to.

13 And then three years later,  
14 or two years later, they finally said to  
15 ZHP, okay, on a going-forward basis, you  
16 finally fixed these problems, we're going  
17 to finally remove you from the import  
18 alert.

19 That's what actually  
20 occurred, right?

21 A. No.

22 MS. DAVIDSON: Objection.

23 THE WITNESS: So the import  
24 alert is actually -- you know, the

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1 import alert has a very specific  
2 purpose. And I'm looking for a  
3 text out of my report which I will  
4 come to.

5 The import alert is there to  
6 prevent potentially violative  
7 product getting into the market.  
8 And it's also, according to FDA,  
9 is to free up its resources so  
10 that it can examine other  
11 shipments.

12 Now, it also -- FDA also  
13 wants a uniform coverage across  
14 the United States, across the  
15 country, and also to put the  
16 responsibility back on the firm.

17 So the issue with this is  
18 that the import alert, which was  
19 initiated, I think, in September,  
20 the import alert was put in place  
21 on the same day FDA asked for a  
22 list of clients of ZHP.

23 APIs, when they are sold,  
24 there is no expiry date for API.

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1 So when you sell a batch of APIs,  
2 the API can be used continuously  
3 until they run out.

4 What FDA wanted to do, very  
5 specifically, was to make sure  
6 that the drug product  
7 manufacturers, who ZHP had no  
8 control over, would not ship those  
9 products to the U.S.

10 The fastest, the easiest and  
11 the most convenient solution is an  
12 import alert.

13 BY MR. SLATER:

14 Q. When I read your report, I  
15 thought you said something to the effect  
16 of once the import alert was lifted, if  
17 ZHP wanted to, it could start re -- it  
18 could start selling its valsartan again,  
19 the valsartan manufactured with the zinc  
20 chloride process.

21 Did you mean to say that in  
22 your report, or did I misread your  
23 report?

24 MS. DAVIDSON: Objection.

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1 THE WITNESS: So the DMF has  
2 not been changed. The DMF is  
3 there and it's acting. If --

4 BY MR. SLATER:

5 Q. So in your opinion, they  
6 can --

7 MS. DAVIDSON: Whoa. He was  
8 in the middle of talking, Adam.

9 THE WITNESS: So if I go  
10 back and look at also on the  
11 subject of, okay, so what happened  
12 and what did they do, Point 98 in  
13 my statement says, In the EIR --  
14 this is the 2018 EIR which  
15 resulted in a response and warning  
16 letter and an import alert -- they  
17 investigated, documented that he  
18 reviewed the stability protocol  
19 for valsartan implemented in 2012  
20 and everything was good.

21 And he says, And noted that  
22 all data reported within  
23 specification, and results were  
24 similar across the U.S. and



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1 non-U.S. market.

2 99. The EIR, the 2018 EIR,  
3 noted that ZHP has an established  
4 quality unit, consists of quality  
5 assurance department and quality  
6 control lab. It further noted  
7 that the firm has established  
8 written procedures for the quality  
9 unit covering supplier  
10 qualification, training, batch  
11 release validation, calibration,  
12 investigation, including deviation  
13 and product recalls, stability  
14 studies and complaints.

15 So they investigated, as  
16 documented, that the quality unit  
17 is functioning well.

18 100. The inspector observed  
19 employees' practices, reviewed  
20 documents and conducted  
21 personal -- personal interviews  
22 with various staff members to  
23 assess whether the firm's quality  
24 system is designed to achieve

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1 sufficient control over the  
2 facility and commercial  
3 manufacturing questions.

4 Through these activities,  
5 she observed the quality unit is  
6 involved in activities, including  
7 but not limited to, review of  
8 manufacturing documents and  
9 approval, product prior to release  
10 qualification and validation  
11 activities, deviations and  
12 investigation and change control  
13 activities.

14 A lot of what resulted in  
15 the warning letter, and a lot of  
16 what went on during the  
17 inspection, was ongoing  
18 investigation.

19 So looking at 98, 99 and  
20 100, the quality unit of ZHP was  
21 on par. It was functioning  
22 according to the GMPs.

23 So the import alert and the  
24 warning letter have to be taken

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1 again in light of the events and  
2 in consideration of what was going  
3 on. ZHP informed FDA that it had  
4 NDMA in its valsartan. FDA came  
5 for an inspection, gave them a set  
6 of observations, and then an  
7 import alert, which effectively  
8 was to prevent material from all  
9 these drug product manufacturers  
10 coming into the U.S., as well as  
11 keeping them on hook.

12 Now, the DMF is still  
13 active. The DMF with zinc  
14 chloride is still active, because  
15 the quality system is functioning  
16 properly.

17 BY MR. SLATER:

18 Q. Is the import of you saying,  
19 after that answer at the end, that DMF,  
20 for the zinc chloride process, is still  
21 in effect, that if ZHP wants to, it can  
22 manufacture and sell valsartan  
23 manufactured with the zinc chloride  
24 process?

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1 MS. DAVIDSON: Objection.

2 BY MR. SLATER:

3 Q. Yes or no?

4 MS. DAVIDSON: Objection.  
5 Enough with the yes-or-no  
6 follow-ups to every question.

7 THE WITNESS: Sorry. I will  
8 not give you a yes-or-no answer.  
9 I'll tell you what is there.

10 ZHP stopped manufacturing  
11 using the process that was  
12 resulting in NDMA in June of 2018.  
13 They immediately stopped.

14 They started looking at  
15 their process. They put it right.

16 And as I said, the DMF is  
17 still active. Are they selling or  
18 not? I have no information about  
19 that. I know that the DMF is  
20 active.

21 BY MR. SLATER:

22 Q. Is ZHP permitted, if it  
23 wants to, today, to manufacture and sell  
24 in the United States valsartan

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1 manufactured with the zinc chloride  
2 process; yes or no?  
3 MS. DAVIDSON: Objection.  
4 THE WITNESS: ZHP is allowed  
5 to sell valsartan against the DMF  
6 which is active.  
7 MR. SLATER: Thank you. We  
8 can take a break. We can go off  
9 the record.  
10 THE WITNESS: Thank you.  
11 VIDEO TECHNICIAN: We're off  
12 the record at 3:10 p.m.  
13 - - -  
14 (Whereupon, a brief recess  
15 was taken.)  
16 - - -  
17 VIDEO TECHNICIAN: We're  
18 back on the record at 3:36 p.m.  
19 BY MR. SLATER:  
20 Q. I'm showing you what was  
21 attached as Exhibit B to your initial  
22 report of December 23, 2022, the list of  
23 materials reviewed and considered.  
24 A. Yes.

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1 Q. Did you read all those  
2 documents?  
3 A. I -- if it's there, I read  
4 it.  
5 Q. And it's your testimony if  
6 it is there you read it cover to cover,  
7 every one of the documents?  
8 A. So some cover to cover, some  
9 several times, some I gleaned through.  
10 Q. Did you read all the  
11 deposition transcripts listed there  
12 completely?  
13 A. I read the deposition  
14 transcripts starting when I started on  
15 this project, yes.  
16 Q. You read every single one of  
17 those deposition transcripts cover to  
18 cover?  
19 MS. DAVIDSON: Objection.  
20 THE WITNESS: So I have read  
21 those depositions, yes.  
22 BY MR. SLATER:  
23 Q. One of the things I saw you  
24 were provided was the expert report and

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1 deposition of David Chesney?  
2 A. Yes.  
3 Q. Did you read those  
4 documents?  
5 A. Yes.  
6 Q. Do you know Mr. Chesney?  
7 A. I know of Mr. Chesney. I  
8 don't know him as an acquaintance or a  
9 friend.  
10 Q. Did you take into account  
11 the opinions that he offered during his  
12 deposition?  
13 MS. DAVIDSON: Objection.  
14 THE WITNESS: Did I take  
15 into account -- I read his  
16 deposition.  
17 BY MR. SLATER:  
18 Q. Were any of the things that  
19 David Chesney said in his deposition of  
20 any significance to you in forming your  
21 opinions in this case?  
22 A. So were they of  
23 significance? Again, we've been there  
24 before. And I said, what do you mean by

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1 "significance," and you said, did I read  
2 it?  
3 So my answer is, based on  
4 that definition, yes, I read it. Did  
5 he -- did I take it into account? Yes, I  
6 did.  
7 Q. Was there anything that  
8 Mr. Chesney testified to where you looked  
9 at it and said, you know, that's  
10 something that's important, I'm going to  
11 rely on that for my opinion? Anything  
12 you can think of?  
13 A. I don't recall.  
14 MR. SLATER: Let's put up  
15 the supplemental list, please. I  
16 guess that would be a new exhibit,  
17 12?  
18 - - -  
19 (Whereupon, Exhibit  
20 Afnan-11, No Bates, Exhibit  
21 B-Materials Reviewed and  
22 Considered (Amended and  
23 Supplemental), was marked for  
24 identification.)

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1 - - -

2 BY MR. SLATER:

3 Q. So now we marked as

4 Exhibit-11 your amended and supplemental

5 list of materials reviewed and

6 considered.

7 Have you seen that document?

8 A. Yes.

9 Q. Does this list everything

10 that you have seen, as of now, relative

11 to this case?

12 A. I believe so.

13 Q. Unless I missed it, I don't

14 see the deposition -- hang on.

15 No, I take it back. I see

16 on the first page that you saw some

17 deposition transcripts of our -- of the

18 plaintiffs' experts, Dr. Hecht, Dr. Bain,

19 Dr. Najafi and Dr. Plunkett.

20 You read those transcripts?

21 A. Yes.

22 Q. Did reading those

23 transcripts have any impact on your

24 opinions in this case?

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1 A. Did they have any impact?

2 So, obviously, if I read a document, I

3 will have to consider what is being asked

4 and what is being said. And if I

5 consider that in my deliberations, does

6 it have an impact? Yes. Does it have a

7 supreme impact, a perfect impact? The

8 answer is -- is no.

9 So, again, I've read them.

10 I've read them. I've looked at the

11 questions, and I've looked at the

12 answers.

13 Q. I'd like you to assume for a

14 second that the information necessary for

15 ZHP to understand the potential formation

16 of NDMA and NDEA in its valsartan

17 manufacturing processes was available and

18 should have been found by the people that

19 were developing that process and then

20 overseeing that process.

21 In other words, I'd like you

22 to assume that Dr. Hecht and Dr. Najafi

23 are correct and that Dr. Xue is incorrect

24 on that point.

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1 Do you understand the

2 hypothetical I'm putting you in?

3 MS. DAVIDSON: I'm sorry, my

4 computer froze, and I missed the

5 hypothetical.

6 Can you read it back?

7 MR. SLATER: I'll do it.

8 BY MR. SLATER:

9 Q. I want you to assume that

10 Dr. Hecht and Dr. Najafi are correct

11 about what ZHP could and should have

12 known about the potential formation of

13 NDMA and NDEA in the manufacturing

14 processes and that Dr. Xue is incorrect

15 as to what ZHP could and should have

16 known, based on what you read in the

17 reports and depositions, okay?

18 A. Okay.

19 Q. If that's the case, then ZHP

20 violated cGMP in failing to test for and

21 identify the presence of the NDMA and

22 NDEA, correct?

23 MS. DAVIDSON: I'm going to

24 object. That's an improper

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1 hypothetical. Incomplete and

2 vague.

3 THE WITNESS: So I'm looking

4 at the totality of the statements

5 by Dr. Hecht and Dr. Najafi. And

6 there are statements that I simply

7 cannot subscribe to. And yet you

8 ask me to hypothetically accept

9 those as correct.

10 If I assume those are

11 correct, then I don't even know

12 whether that would exclude

13 Dr. Xue's conclusions.

14 However, I cannot -- I

15 struggle to accept statements made

16 by Dr. Najafi and Dr. Hecht.

17 That's my struggle.

18 BY MR. SLATER:

19 Q. If ZHP could have and should

20 have identified the potential formation

21 of NDMA and NDEA in the TEA with sodium

22 nitrite quenching and zinc chloride

23 processes and then did absolutely no

24 testing to try to identify whether there

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1 was NDMA or NDEA, they would have  
2 violated cGMPs, correct?

3 MS. DAVIDSON: Objection.

4 THE WITNESS: If they could  
5 have and they should have, that  
6 they -- the struggle that I have  
7 is, again, as per FDA's statement,  
8 nobody knew -- or, let's be  
9 specific, neither industry nor the  
10 regulators knew, and it's not only  
11 FDA it's also the European  
12 regulators, they did not know.

13 And, therefore, if you do  
14 not know, since they didn't know,  
15 they weren't looking for it.

16 So, you know, even based on  
17 a hypothesis or a hypothetical --  
18 not hypothesis, a hypothetical  
19 that a firm knew, what about FDA?  
20 Was FDA colluding with them? No.  
21 FDA didn't know either because the  
22 knowledge of the process was not  
23 known at that time. And if it was  
24 not known, then they would not

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1 have tested for it.

2 In fact, again, as stated by  
3 the FDA, the test methods were not  
4 there for detecting NDMA because  
5 nobody expected that NDMA was  
6 being formed in these processes.

7 BY MR. SLATER:

8 Q. Is there any state of facts  
9 that I can tell you as to what ZHP --  
10 rephrase.

11 Is there any set of facts  
12 that I can present to you as a  
13 hypothetical as to ZHP's knowledge about  
14 the manufacturing processes specific to  
15 the formation of NDMA and NDEA where you  
16 would say, well, if ZHP had known that,  
17 then, yes, I agree they violated cGMP in  
18 connection with those manufacturing  
19 processes?

20 What would I have to show  
21 you for you to say, yes, I can say they  
22 violated cGMPs?

23 MS. DAVIDSON: Objection.  
24 Vague.

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1 THE WITNESS: I'm -- I'm  
2 stuck at the beginning of your  
3 question, where you say any set of  
4 facts as hypotheticals. Facts are  
5 not hypotheticals. Facts are  
6 facts.

7 So the question is, what  
8 facts are there that you would  
9 like to present to me and I will  
10 respond to it?

11 My struggle is with  
12 hypotheticals. Yes, hypotheticals  
13 can go whichever way they are  
14 presented. But the case here is  
15 not based on hypotheticals.

16 If I'm in a deposition, my  
17 goal, my objective, is for my  
18 testimony to be accurate.

19 BY MR. SLATER:

20 Q. Is it your opinion that even  
21 if ZHP had known that NDMA and NDEA could  
22 form in these manufacturing processes,  
23 knew how the -- let me ask it  
24 differently.

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1 If Ethicon -- Ethicon,  
2 that's funny.

3 If ZHP knew that -- let me  
4 start over.

5 If ZHP knew that the  
6 substances they were using in the sodium  
7 nitrite with quenching and zinc chloride  
8 processes could have the reactions that  
9 they ultimately were proven to have and  
10 that NDMA and NDEA could potentially  
11 form, as it ultimately did, if they had  
12 identified that, if they had identified  
13 those potential reactions, identified  
14 that those chemicals and substances would  
15 be in the process and knew that this  
16 could happen, if they knew that and then  
17 did not test to see if there was NDMA and  
18 NDEA in those -- being produced by those  
19 processes, under that hypothetical, would  
20 you say that, well, if they knew those  
21 things, yes, they violated cGMP by not  
22 testing for NDMA and NDEA?

23 MS. DAVIDSON: Objection.  
24 THE WITNESS: Again, that's



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1 a hypothetical. So I really need  
2 to characterize my response  
3 correctly.  
4 If any firm knew of its  
5 processes resulting in mutagenic  
6 properties, I believe that firm  
7 would inform the regulators and  
8 would not continue production,  
9 which is what ZHP did.  
10 BY MR. SLATER:  
11 Q. Taking your response, if ZHP  
12 knew that the NDMA and NDEA could  
13 potentially be formed but they weren't  
14 sure if it was or was not being formed  
15 and the only way to know would be to  
16 actually test the valsartan that was  
17 being produced to see if there was NDMA  
18 and NDEA but they never did the test,  
19 under that circumstance, would they  
20 violate cGMP?  
21 MS. DAVIDSON: Objection.  
22 THE WITNESS: So if a firm,  
23 ZHP, knew that NDEA and NDMA were  
24 being formed in one of the

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1 processes, then according to the  
2 existing quality system  
3 requirements of any firm, they  
4 would have to raise a deviation,  
5 they would have to stop it --  
6 since it was NDMA and NDEA, they  
7 would then effectively stop  
8 manufacture and stop shipping.  
9 This happened in June 2018  
10 when they became aware. Prior to  
11 that, they didn't know.  
12 BY MR. SLATER:  
13 Q. If they understood that it  
14 was possible for the NDMA and NDEA to  
15 form, if they understood that and  
16 understood the potential mechanism of  
17 formation that ultimately was proven to  
18 have occurred, would cGMPs, at that time,  
19 have required ZHP to then do tests then  
20 to see if there was NDMA and NDEA being  
21 created?  
22 MS. DAVIDSON: Objection. I  
23 think this was asked and answered.  
24 If it's different, I

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1 misunderstood.  
2 THE WITNESS: So it's  
3 worthwhile to look at the way the  
4 pharmaceutical industry operates,  
5 or is expected to operate.  
6 A firm, ZHP included, would  
7 develop a drug substance process  
8 away from the manufacturing  
9 facility, in an R&D setting. They  
10 would investigate the process.  
11 They would assess whether the  
12 process is likely to produce,  
13 specifically, NDMA and NDEA.  
14 And if there is -- their  
15 assessment is not effectively  
16 looking -- if their assessment  
17 says, the potential of forming  
18 these impurities is not there, as  
19 per GMP practices, there is no  
20 obligation to go digging and  
21 looking for those impurities.  
22 All of that is documented in  
23 ZHP. ZHP documented the process  
24 of looking at the process, looking

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1 at potential impurities and  
2 actually testing for what they  
3 knew and coming up with a list of  
4 them which was compliant to FDA  
5 requirements.  
6 They submitted that change  
7 as a change to the DMF to FDA.  
8 That was reviewed by FDA. FDA  
9 accepted the change.  
10 That process, then, got --  
11 effectively, in 2018, the client,  
12 a potential client -- not a  
13 client, a potential client,  
14 Novartis, told them that, hey,  
15 what is this peak? Let's look at  
16 it. They looked at it, they said  
17 it's NDMA.  
18 Immediately, they took  
19 action of reporting to FDA,  
20 stopping the process, stop  
21 selling, did the recall, changed  
22 the process, submitted the process  
23 to the FDA.  
24 That's why the DMF is still



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1 active. The DMF is active with a  
2 change to the process.  
3 BY MR. SLATER:  
4 Q. Can you answer my question,  
5 please?  
6 Doctor, can you please  
7 answer my question? I would really  
8 appreciate it.  
9 A. So that I'm clear, can you  
10 please repeat your question? Because I  
11 believe I've answered it.  
12 Q. If ZHP -- actually, you know  
13 what, I'll ask the court reporter to read  
14 it back to you so we'll get it exact.  
15 And I really ask you, can  
16 you just answer the question I actually  
17 asked you?  
18 COURT REPORTER: I think  
19 Jessica was kicked off.  
20 THE WITNESS: I would like  
21 to wait until she's back, please.  
22 MR. SLATER: Go off the  
23 record.  
24 VIDEO TECHNICIAN: We're off

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1 the record at 3:56 p.m.  
2 - - -  
3 (Whereupon, a brief recess  
4 was taken.)  
5 - - -  
6 VIDEO TECHNICIAN: We're  
7 back on the record at 4:04 p.m.  
8 BY MR. SLATER:  
9 Q. If ZHP understood the  
10 possible formation of NDMA and NDEA with  
11 its valsartan processes -- let me start  
12 over.  
13 If ZHP had understood that  
14 the substances it was introducing into  
15 the valsartan manufacturing processes,  
16 specifically TEA with sodium nitrite  
17 quenching and zinc chloride, could  
18 potentially cause the formation of NDMA  
19 and NDEA, were they required by cGMP to  
20 test to see if NDMA and NDEA was formed?  
21 MS. DAVIDSON: Objection.  
22 THE WITNESS: So I did  
23 respond to that question.  
24 The response was that

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1 developing the process happens  
2 away from the manufacturing  
3 facility.  
4 When ZHP was developing the  
5 process away from the  
6 manufacturing facility, they did  
7 consider the formation of  
8 impurities. And at that time, as  
9 per FDA's statement that neither  
10 FDA nor industry understood the  
11 pathway for formation of NDMAs,  
12 these were not considered nor  
13 detected.  
14 So -- and, again, continuing  
15 with what I said before,  
16 development of a process is not a  
17 GMP process, it's a non-GMP. It's  
18 not regulated.  
19 Once it is approved by the  
20 regulator and it's a process which  
21 is validated, then it becomes a  
22 GMP process and it's then in the  
23 manufacturing markets -- markets  
24 process.

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1 So your question asks --  
2 your question has hypotheticals  
3 that, you know, I would have to  
4 conclude to do away with all facts  
5 and work in the ether of  
6 hypotheticals.  
7 BY MR. SLATER:  
8 Q. When the process changes  
9 took place, that's governed by GMP, it's  
10 called change control, right?  
11 A. Yes.  
12 Q. If, as part of the process  
13 changes, ZHP had realized that the  
14 chemicals they were using and the  
15 substances they were using could form  
16 NDMA and NDEA under the conditions of  
17 those processes, if they had realized  
18 that, were they required, by cGMPs, to  
19 test to see if there was NDMA or NDEA in  
20 the valsartan?  
21 A. So giving you, again, almost  
22 a repeat answer.  
23 For ZHP to actually change  
24 their process using a change control

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1 procedure, they cannot do it in the  
2 manufacturing facility.  
3 What they have to do is  
4 develop the process away from the  
5 manufacturing facility, then validate the  
6 process at scale in the manufacturing  
7 facility and discard that batch.  
8 Then submit that to the  
9 agency, get approval from the agency and  
10 EDQM, because that was also the customer,  
11 and then proceed to manufacture for the  
12 market.  
13 So it's not a case of  
14 suddenly one day they decide to implement  
15 a change based on a change control.  
16 There was two years of investigations and  
17 studies carried out before that change  
18 control was actually implemented, which  
19 was after approval by the FDA.  
20 Q. I'll ask the question  
21 differently.  
22 If ZHP had realized, at any  
23 point between 2011 and 2018, that their  
24 manufacturing processes for the

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1 manufacture of valsartan, the TEA with  
2 sodium nitrite quenching and the zinc  
3 chloride process, could potentially be  
4 creating NDMA and NDEA, as soon as they  
5 made that -- had that revelation that the  
6 process could create those genotoxic  
7 impurities, would they have been required  
8 to test to see if there was NDMA and  
9 NDEA?  
10 MS. DAVIDSON: Objection.  
11 Same objections.  
12 THE WITNESS: So when  
13 they -- when ZHP identified  
14 presence of NDMA in its valsartan,  
15 it actually stopped manufacture.  
16 It informed the FDA. It put a  
17 stop at the process on hold. It  
18 put the stock on hold. It  
19 requested FDA for a recall  
20 classification. So they did all  
21 of that.  
22 BY MR. SLATER:  
23 Q. That's great. That's not  
24 what I asked you, though. I didn't ask

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1 you when they figured out that it was  
2 there.  
3 I said if they figured out  
4 that it was possibly forming, did they  
5 need to do the tests, at that point in  
6 time when they first realized it could  
7 possibly be forming, to see if there was  
8 NDMA or NDEA in the drug substance; yes  
9 or no?  
10 MS. DAVIDSON: I'm going to  
11 object, because you interrupted  
12 the witness and are asking the  
13 same question again. So it's  
14 asked and answered.  
15 But please don't interrupt  
16 Dr. Afnan.  
17 THE WITNESS: You know, so  
18 if I'd like to go to my report. I  
19 would like -- because I address  
20 this in my report, and I think  
21 that is probably -- if you go to  
22 Number 80 in my report.  
23 It says, ZHP performed  
24 extensive research and testing for

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1 more than two years before  
2 submitting the drug master file  
3 amendment containing zinc chloride  
4 process. On June 16th, 2011, ZHP  
5 issued a summary of its test  
6 production using the zinc chloride  
7 process that noted overall the  
8 crude isomer of the tri production  
9 batches were maintained at 1 to 2  
10 percent and there were no  
11 individual impurities that were  
12 difficult to remove by  
13 crystallization and purification.  
14 Therefore, the product quality  
15 also met the expected  
16 requirements.  
17 Likewise, an internal change  
18 request form, dated November 27,  
19 2011, stated that the new process  
20 solves the problem of production  
21 stability and Valine methyl ester  
22 condensation and pentanoyl reaction  
23 and the new reaction system of  
24 zinc chloride and DMF for

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1 tetrazole reaction is developed,  
2 which greatly improves the  
3 conversion rate of raw materials,  
4 improves the yields, reduces --  
5 reduces -- improves and -- it says  
6 reduces the heat and reduces the  
7 free waste. In addition, by  
8 optimizing the saponification  
9 condition, the assay of isomer in  
10 valsartan crude is reduced and the  
11 quality of valsartan is improved.

12 Through a large number of  
13 experimental results about  
14 optimizing process and combined  
15 with theoretical analysis, the  
16 synthesis route of new process and  
17 critical process parameters are  
18 initially -- initially determined  
19 by Huahai and the preliminary  
20 analysis and evaluation of  
21 impurities in the new process is  
22 completed, confirming that the  
23 quality product risk is  
24 controlled.

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1 At the same time, the safety  
2 risk brought by process changes  
3 are also evaluated by Huahai  
4 confirming that the new process is  
5 safe and reliable, essentially.

6 According to the above  
7 analysis, the zinc chloride  
8 process is stable and reliable and  
9 has the conditions for further  
10 validation of production. The  
11 changes of original process are  
12 applied and a new process  
13 validation is organized.

14 And all of this was  
15 submitted to FDA.

16 BY MR. SLATER:

17 Q. Answer my question, please.

18 I'm going to ask you now --  
19 I know your counsel is not going to tell  
20 you that what you just did is completely  
21 obstructive and not responsive. I  
22 realize that. I'm just -- I'm just  
23 telling you that this is not appropriate.  
24 I asked you a question.

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1 Your counsel is making crazy faces. I  
2 don't know why.  
3 I asked you a very  
4 straightforward question and you went and  
5 read me this whole section of your report  
6 for five minutes. I'm not really sure  
7 why you think that's beneficial to your  
8 position here.

9 So can you now answer my  
10 question? Which what you just read has  
11 nothing to do with.

12 Can you please answer my  
13 question?

14 A. What was your question?

15 Q. It's literally a yes-or-no  
16 question, a very straightforward  
17 hypothetical.

18 Can you just answer it,  
19 please?

20 MS. DAVIDSON: There's no  
21 question pending. He answered the  
22 question you asked.

23 If you want to ask another  
24 question, please go ahead.

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1 BY MR. SLATER:

2 Q. I asked the question.

3 Doctor, please just answer  
4 it. Come on.

5 MS. DAVIDSON: Objection.  
6 If you want him to answer a  
7 question --

8 MR. SLATER: Don't tell me  
9 to ask a question, please. Don't  
10 give me instructions. I don't  
11 need to be told what to do.

12 MS. DAVIDSON: There's no  
13 question pending. You asked a  
14 question. He answered it.

15 MR. SLATER: I don't want to  
16 talk to you. I don't want to  
17 speak to you. It's not helpful.  
18 It's wasting more time.

19 BY MR. SLATER:

20 Q. So, Doctor, answer my  
21 question, please.

22 MS. DAVIDSON:  
23 Unfortunately, I'm the person  
24 defending this deposition. You're

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1 interrupting me. You're being  
2 rude.  
3 Dr. Afnan answered your  
4 question.  
5 If you have another  
6 question, ask another question.  
7 But you can't just say, I don't  
8 like your answer, give me another  
9 one.  
10 MR. SLATER: All right,  
11 counsel. You stand behind that  
12 being responsive. That's fine.  
13 BY MR. SLATER:  
14 Q. Now, Doctor, answer my  
15 question.  
16 If ZHP, at any point between  
17 2011 and 2018, realized that their  
18 manufacturing processes for valsartan  
19 could potentially be creating NDMA and  
20 NDEA and they realized what the potential  
21 mechanism of formation was, at that  
22 point, were they required to test to see  
23 if there was NDMA or NDEA in the  
24 valsartan; yes or no?

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1 MS. DAVIDSON: Objection.  
2 THE WITNESS: I'm afraid I  
3 can't give you a yes-or-no answer.  
4 So I'll give you an answer.  
5 The answer is, based on the  
6 hypotheticals that you have posed  
7 and the assumptions that you have  
8 made, the answer would be yes.  
9 But this is not the case  
10 here. I do not subscribe to the  
11 hypotheticals. And I do not  
12 subscribe to the assumptions.  
13 And, again, this was not the  
14 case here with ZHP prior to June  
15 2018.  
16 BY MR. SLATER:  
17 Q. There came a date when  
18 Novartis advised ZHP that Novartis  
19 thought there might be NDMA in the  
20 valsartan, correct?  
21 A. Sorry. Can you ask the  
22 first part? It just got cut out.  
23 Q. Novartis notified ZHP, in  
24 2018, that it believed that there might

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1 be NDMA in ZHP's valsartan, correct?  
2 A. Novartis informed ZHP  
3 that -- on 6th of June, informed ZHP that  
4 they had asked -- to investigate an  
5 unknown impurity. ZHP also, in parallel,  
6 started an investigation of that same  
7 issue.  
8 So it was actually then that  
9 they both came to the same conclusion.  
10 And Novartis actually doesn't say here  
11 NDMA, Novartis says this is potentially  
12 NDMA.  
13 Q. Could ZHP have figured out  
14 that there was NDMA in its valsartan  
15 without Novartis's involvement? Would  
16 that have been possible for ZHP to do  
17 that all by itself?  
18 MS. DAVIDSON: Objection.  
19 THE WITNESS: This was a  
20 manufacturing process which had  
21 been approved by the Europeans and  
22 FDA. The analytical method was  
23 effectively GC FID that was not  
24 detecting NDMA's.

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1 FDA says that. The methods  
2 were not there. And nobody knew  
3 about the formation of NDMA's in  
4 valsartan, so.  
5 BY MR. SLATER:  
6 Q. Is an important part of the  
7 basis for your opinion what the FDA said  
8 in the statements that it issued about  
9 this situation, about what people knew  
10 and what people didn't know, and  
11 different methods and all the things that  
12 the FDA has said? Is that an important  
13 part of your opinion?  
14 A. Yes.  
15 Q. Could ZHP have figured out  
16 that there was NDMA in the valsartan  
17 without Novartis's assistance? Was that  
18 possible, that they could have done it on  
19 their own?  
20 MS. DAVIDSON: Objection.  
21 THE WITNESS: The question  
22 is whether ZHP could have  
23 identified it? And the answer is,  
24 what was the justification to go



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<p>1 and look for it?</p> <p>2 Novartis had a reason to</p> <p>3 look for it, based on what has</p> <p>4 been shared, which is, here is a</p> <p>5 little peak which is coming up,</p> <p>6 and unknown impurity after</p> <p>7 targeting, and it was below the .1</p> <p>8 percent and Novartis said, can we</p> <p>9 look at that one?</p> <p>10 Now, there were other</p> <p>11 unknown peaks as well, which</p> <p>12 Novartis did not look at. But</p> <p>13 Novartis decided to look at that.</p> <p>14 BY MR. SLATER:</p> <p>15 Q. ZHP could have noticed that</p> <p>16 peak and investigated that peak without</p> <p>17 being told anything by Novartis; that was</p> <p>18 possible, right?</p> <p>19 A. ZHP was operating according</p> <p>20 to Q3A, which said you can have unknown</p> <p>21 impurities below .1 percent.</p> <p>22 So the answer is, they could</p> <p>23 have. But they had no reason, no</p> <p>24 justification, no cause to look for that</p>	<p>1 just a lot smarter than the people at</p> <p>2 ZHP?</p> <p>3 MS. DAVIDSON: Objection.</p> <p>4 BY MR. SLATER:</p> <p>5 Q. Is that why they figured it</p> <p>6 out and ZHP didn't?</p> <p>7 MS. DAVIDSON: I'm sorry. I</p> <p>8 objected after the first question</p> <p>9 because I thought there was just</p> <p>10 one question. And then there was</p> <p>11 a second question.</p> <p>12 I object to both.</p> <p>13 THE WITNESS: I cannot</p> <p>14 comment whatsoever on that.</p> <p>15 That's beyond the scope of my</p> <p>16 work, to guess who is smarter.</p> <p>17 BY MR. SLATER:</p> <p>18 Q. ZHP could have looked at the</p> <p>19 unknown peaks and could have investigated</p> <p>20 them and could have figured out that one</p> <p>21 of those peaks represented NDMA if it had</p> <p>22 chosen to do a thorough investigation</p> <p>23 like Novartis did, correct?</p> <p>24 MS. DAVIDSON: Objection.</p>
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<p>1 impurity and that peak.</p> <p>2 Q. If ZHP had been more careful</p> <p>3 than it actually was and had decided to</p> <p>4 investigate that NDMA peak, which it had</p> <p>5 not identified yet, ZHP could have</p> <p>6 figured out that it was NDMA, right?</p> <p>7 That was something that was technically</p> <p>8 feasible for it to do, correct?</p> <p>9 MS. DAVIDSON: Objection.</p> <p>10 THE WITNESS: So if you know</p> <p>11 what you're looking for, it is</p> <p>12 feasible to do it. ZHP looked</p> <p>13 with GCMS and actually -- so</p> <p>14 that's how the conversation with</p> <p>15 Novartis started.</p> <p>16 Novartis asked for, can you</p> <p>17 send the data, the spectra for</p> <p>18 that peak? Which they did and</p> <p>19 they sent in. And that</p> <p>20 effectively was not NDMA; that was</p> <p>21 the conclusion that they both came</p> <p>22 to.</p> <p>23 BY MR. SLATER:</p> <p>24 Q. Were the people at Novartis</p>	<p>1 BY MR. SLATER:</p> <p>2 Q. ZHP had the ability to do</p> <p>3 that if it chose to go through that</p> <p>4 process, correct?</p> <p>5 MS. DAVIDSON: Again, I keep</p> <p>6 objecting after one question and</p> <p>7 then a second question gets asked.</p> <p>8 I'm objecting to both.</p> <p>9 THE WITNESS: ZHP had no</p> <p>10 reason to investigate, because</p> <p>11 they were adhering to the GMPs and</p> <p>12 the requirements of FDA and EDQM.</p> <p>13 They were following the GMPs.</p> <p>14 And, therefore, what was</p> <p>15 going on was that you were</p> <p>16 allowed -- or ZHP was allowed to</p> <p>17 have unknown impurities below .1</p> <p>18 percent. This is common practice</p> <p>19 in industry.</p> <p>20 BY MR. SLATER:</p> <p>21 Q. You keep explaining this to</p> <p>22 me. It's a very simple question.</p> <p>23 Could ZHP have identified</p> <p>24 the NDMA peak without Novartis's help if</p>



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1 ZHP had actually gone through the thought  
2 process that Novartis did? Was that  
3 possible?

4 MS. DAVIDSON: Objection.  
5 Asked and answered.

6 THE WITNESS: It's a simple  
7 question, and you don't like my  
8 answer.

9 Because my answer is, there  
10 was no cause for ZHP to  
11 investigate the unknown peaks.  
12 There had been no cause from the  
13 regulators to investigate those  
14 unknown peaks, not -- two  
15 regulators.

16 BY MR. SLATER:

17 Q. Then why did Novartis  
18 investigate the unknown peaks?

19 A. Novartis was -- sorry.

20 THE WITNESS: Jessica?

21 MR. SLATER: Are you asking  
22 for an objection, Doctor? I  
23 mean --

24 THE WITNESS: If she wants

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1 to.

2 MS. DAVIDSON: He was  
3 apologizing for the fact that I  
4 had asked earlier to wait before  
5 he answered questions.

6 I would have objected to the  
7 question. But go ahead.

8 MR. SLATER: I have another  
9 question. I'm sure you would  
10 have.

11 BY MR. SLATER:

12 Q. Did Novartis do something  
13 that was super human in the  
14 pharmaceutical field --

15 MS. DAVIDSON: Objection.

16 BY MR. SLATER:

17 Q. -- that no other company  
18 would have ever done, but we just --  
19 everybody just lucked out that Novartis  
20 happened to get involved?

21 MS. DAVIDSON: Objection.

22 BY MR. SLATER:

23 Q. Answer the question, please;  
24 yes or no.

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1 A. I can't answer whether  
2 Novartis was super human or not.

3 Q. Okay. Then you can't answer  
4 the question. That's fine.

5 Doctor, one of the very  
6 important foundational assumptions in  
7 your opinion is that Q3A allowed the NDMA  
8 peak to go uninvestigated because it was  
9 below .1 percent.

10 Do I understand that opinion  
11 correctly?

12 A. No, you do not understand  
13 that correctly. I have never said that  
14 Q3A allows NDMA to be ignored.

15 If you see it in Q3A, I  
16 would appreciate you showing it to me.

17 Q. You've told -- you've told  
18 me that the NDMA peak was so small and it  
19 was below .1 percent, so ZHP was not  
20 required to investigate what the cause of  
21 that peak was; that's your opinion,  
22 right?

23 MS. DAVIDSON: Objection.  
24 That completely mischaracterizes

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1 his testimony.

2 THE WITNESS: It does. No,  
3 that's not what I said.

4 BY MR. SLATER:

5 Q. Okay. So was ZHP required  
6 to investigate what was behind that peak  
7 that ultimately turned out to be NDMA  
8 under cGMP; yes or no?

9 A. I have responded to that  
10 question.

11 Q. Yes or no?

12 MS. DAVIDSON: Objection.  
13 Yes or no is not a question.

14 THE WITNESS: Yeah, I cannot  
15 give you a yes-or-no answer. And  
16 the response I've given you, you  
17 don't like.

18 BY MR. SLATER:

19 Q. That's fine.

20 MR. SLATER: This is  
21 Exhibit-12, right? Just let me  
22 know when you know.

23 MS. DAVIDSON: Are you  
24 talking to us?

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1 MR. SLATER: No, I'm not  
2 talking to you.  
3 MS. DAVIDSON: Okay.  
4 - - -  
5 (Whereupon, Exhibit  
6 Afnan-12, No Bates, 10/25/06  
7 Impurities in New Drug Substances  
8 Q3A(R2), was marked for  
9 identification.)  
10 - - -  
11 BY MR. SLATER:  
12 Q. This is Exhibit-12.  
13 A. Yes.  
14 Q. We've put on the screen the  
15 ICH Q3A.  
16 Do you see that?  
17 A. Yes.  
18 Q. That's the Q3A that you've  
19 been -- or the Q3 that you've been  
20 referring to the whole deposition, right?  
21 A. Yes.  
22 MS. DAVIDSON: Objection.  
23 Please, Dr. Afnan --  
24 THE WITNESS: Yes.

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1 MS. DAVIDSON: -- give me  
2 time to object.  
3 BY MR. SLATER:  
4 Q. Even though this says that  
5 it's impurities in new drug substances,  
6 you're aware that there's a guidance for  
7 industry, from June 2009, that indicates  
8 that this is also applicable to ANDAs,  
9 right?  
10 A. Please tell me which  
11 guidance.  
12 Q. Let me just ask you this  
13 way: You, as the expert on GMP, do you  
14 know whether or not this guidance is also  
15 applicable not only to new drug  
16 substances but also to ANDAs?  
17 A. Q3A, right?  
18 Q. Yep.  
19 A. Yes, it is.  
20 Q. Okay. This is an important  
21 document that you're relying on in  
22 forming your opinions, right?  
23 A. Yes.  
24 Q. Let's go to Page 2, Section

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1 3.1.  
2 Under Section 3, which is  
3 titled, Rationale for the Reporting and  
4 Control of Impurities, there's 3.1,  
5 Organic Impurities.  
6 Do you see that?  
7 A. Yes.  
8 Q. This says, The  
9 application -- The applicant should --  
10 rephrase.  
11 3.1 says, The applicant  
12 should summarize the actual and potential  
13 impurities most likely to arise during  
14 the synthesis, purification and storage  
15 of the new drug substance. This summary  
16 should be based on sound scientific  
17 appraisal of the chemical reactions  
18 involved in the synthesis, impurities  
19 associated with raw materials that could  
20 contribute to the impurity profile of the  
21 new drug substance, and possible  
22 degradation products.  
23 Do you see that?  
24 A. Yes.

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1 Q. So according to this  
2 standard, among other things, ZHP was  
3 required to make a sound scientific  
4 appraisal of impurities associated with  
5 the raw materials, correct?  
6 A. Yes.  
7 Q. And, for example, with DMF  
8 that would include dimethylamine; that  
9 would be an impurity associated with a  
10 raw material, right?  
11 MS. DAVIDSON: Objection.  
12 BY MR. SLATER:  
13 Q. Right, Doctor?  
14 A. Okay. Yes.  
15 Q. Possible degradation  
16 products, that's another thing that this  
17 required ZHP to make a sound scientific  
18 appraisal of, right?  
19 MS. DAVIDSON: Objection.  
20 THE WITNESS: They did.  
21 BY MR. SLATER:  
22 Q. That's what this document  
23 says they were required to do.  
24 I didn't ask what they did,

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1 Doctor. So let's now start answering my  
2 questions, when I'm down to a few hours.  
3 A. Okay.  
4 MS. DAVIDSON: Objection.  
5 If that's a question.  
6 BY MR. SLATER:  
7 Q. It says, They were also  
8 required to make a sound scientific  
9 appraisal of possible degradation  
10 products, correct?  
11 MS. DAVIDSON: Objection.  
12 Misstates the document.  
13 BY MR. SLATER:  
14 Q. That's what it says, right?  
15 MS. DAVIDSON: Objection.  
16 THE WITNESS: It says, The  
17 summary should be based on sound  
18 scientific appraisal of the  
19 chemical reactions involved in the  
20 synthesis, impurities associated  
21 with the raw materials that could  
22 contribute to the impurity profile  
23 of the new drug substance, and  
24 possible degradation products.

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1 BY MR. SLATER:  
2 Q. Look down now two more  
3 paragraphs.  
4 There's a paragraph at the  
5 bottom of this section that starts --  
6 MR. SLATER: You've got to  
7 scroll down a little bit, Chris.  
8 BY MR. SLATER:  
9 Q. Looking now at the last  
10 paragraph in Section 3.1, it says,  
11 Identification of impurities present at  
12 an apparent level of not more than, less  
13 than or equal to, the identification  
14 threshold is generally not considered  
15 necessary.  
16 Do you see that?  
17 A. Yes.  
18 Q. And that's one of the  
19 important things that you've been relying  
20 on throughout your testimony today as to  
21 why you believe ZHP did not have to do  
22 any tests to identify the peak that  
23 turned out to be NDMA, correct?  
24 MS. DAVIDSON: Objection.

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1 That misstates his testimony  
2 again.  
3 BY MR. SLATER:  
4 Q. Correct?  
5 A. I do not rely only and  
6 solely on this statement which you have  
7 here.  
8 I believe ZHP did do a  
9 thorough job of looking at its processes.  
10 Q. Did ZHP ever, to your  
11 knowledge, try to figure out what the  
12 peak was, the one that was NDMA, that we  
13 later learned was NDMA, did they ever try  
14 to identify what that peak was before  
15 Novartis got in touch with them; yes or  
16 no?  
17 It's a factual question, did  
18 they or didn't they?  
19 MS. DAVIDSON: Objection.  
20 THE WITNESS: The answer is  
21 right at the top of the page. If  
22 you scroll to just below 3.1,  
23 please.  
24 BY MR. SLATER:

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1 Q. Doctor, I asked if they  
2 tried to identify what that peak was.  
3 This document doesn't talk about ZHP.  
4 Did they try to identify  
5 what that peak was or not; yes or no?  
6 MS. DAVIDSON: You  
7 interrupted the witness. And I'm  
8 objecting.  
9 MR. SLATER: How about you  
10 ask your witness, please, to  
11 answer the question directly, as  
12 opposed to asking to talk about  
13 this document where the answer is  
14 not found.  
15 THE WITNESS: You point me  
16 to this document and you said,  
17 based on this, they should have.  
18 And I'm pointing --  
19 BY MR. SLATER:  
20 Q. That's not what I asked you.  
21 My question was very direct, Doctor.  
22 I asked you is --  
23 A. You --  
24 Q. -- there anything that

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1 you've seen indicating that ZHP ever  
2 tried to identify what that NDMA peak was  
3 before June of 2018?

4 A. The applicant should  
5 summarize the actual and potential  
6 impurities most likely to arise during  
7 the synthesis, purification and storage  
8 of the new product. This summary should  
9 be based on sound scientific appraisal.

10 They did do that.

11 Based on that -- based on  
12 that scientific appraisal by ZHP over two  
13 years, as I have read to you a few  
14 minutes ago, maybe ten minutes ago, as I  
15 read that, this was done.

16 Q. So you're saying that ZHP  
17 actually evaluated the unknown peak that  
18 later turned out to be NDMA --

19 MS. DAVIDSON: Objection.

20 BY MR. SLATER:

21 Q. -- to try to figure out what  
22 it was before June of 2018?

23 MS. DAVIDSON: Objection.

24 THE WITNESS: That's not

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1 was that turned out to be NDMA before  
2 Novartis got in touch with it?

3 As a matter of fact, yes or  
4 no, did they actually focus on that peak  
5 and try to identify what it was at any  
6 point before Novartis raised an issue  
7 about it; yes or no?

8 MS. DAVIDSON: Objection.

9 THE WITNESS: There were  
10 customer requests about peaks --  
11 unknown peaks which was -- this  
12 was one of them that ZHP had  
13 shared information with.

14 Even with this peak, which  
15 is effectively a peak on top of  
16 another one, was requested by  
17 Novartis, and ZHP provided the  
18 information to Novartis.

19 So did they try? Yes.

20 BY MR. SLATER:

21 Q. Did other customers identify  
22 that peak and ask what it was, the NDMA  
23 peak, at any point before Novartis did in  
24 2018; yes or no?

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1 what I said.

2 BY MR. SLATER:

3 Q. Well, how about you just  
4 give me a straight answer to the  
5 question. I don't understand why you  
6 can't just say yes or no.

7 Did they or didn't they try  
8 to identify that peak?

9 MS. DAVIDSON: Objection.

10 THE WITNESS: There was no  
11 regulatory requirement, there was  
12 no scientific obligation to  
13 identify the peak.

14 The reason was because they  
15 looked at the process, and based  
16 on the process, which they looked  
17 at, the prediction was that there  
18 is no undesirable impurity present  
19 in this process. Therefore, the  
20 unknowns would not be required to  
21 be investigated.

22 BY MR. SLATER:

23 Q. Did ZHP ever, to your  
24 knowledge, try to identify what that peak

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1 MS. DAVIDSON: Objection.

2 THE WITNESS: If you had  
3 allowed me to complete my  
4 response, I would have told you  
5 that this was not a question about  
6 is it an NDMA or not.

7 The question was, can you  
8 provide us with the data as to  
9 what this peak is? And ZHP  
10 investigated, reported it to them,  
11 and they accepted it.

12 BY MR. SLATER:

13 Q. Who?

14 A. The clients.

15 Q. Which one?

16 A. There were multiple  
17 questions that came from different  
18 clients, and that's what they did.

19 Q. Multiple clients asked  
20 questions about unknown peaks, including  
21 that peak that turned out to be NDMA?

22 MS. DAVIDSON: Objection.

23 Misstates his testimony.

24 Dr. Afnan, give me a minute.

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1 MR. SLATER: I'll withdraw  
2 that question, actually.  
3 MS. DAVIDSON: Okay.  
4 MR. SLATER: We'll live with  
5 the testimony.  
6 BY MR. SLATER:  
7 Q. All right. Let's go back to  
8 the document.  
9 Looking at the paragraph at  
10 the end of 3.1, it says, Identification  
11 of impurities present at an apparent  
12 level of not more than, less than or  
13 equal to the identification threshold is  
14 generally not considered necessary.  
15 However, analytical procedures should be  
16 developed for those potential impurities  
17 that are expected to be unusually potent,  
18 producing toxic or pharmacological  
19 effects at a level not more than, less  
20 than or equal to the identification  
21 threshold. All impurities should be  
22 qualified as described later in this  
23 guideline.  
24 Do you see what I just read?

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1 A. Yes.  
2 Q. The potential impurities  
3 that are expected to be unusually potent  
4 would include N-nitroso compounds,  
5 correct?  
6 MS. DAVIDSON: Objection.  
7 THE WITNESS: N-nitroso  
8 compounds are compounds of cohorts  
9 of interest.  
10 BY MR. SLATER:  
11 Q. Let's go to Page 4, Section  
12 6.  
13 Looking at Section 6,  
14 Listing of Impurities and Specifications.  
15 I want to go now to the second paragraph.  
16 About halfway down that  
17 paragraph, it says, For impurities known  
18 to be unusually potent or to produce  
19 toxic or unexpected pharmacological  
20 effects, the quantitation/detection limit  
21 of the analytical procedures should be  
22 commensurate with the level at which the  
23 impurities should be controlled. For  
24 unidentified impurities, the procedure

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1 used and assumptions made in establishing  
2 the level of the impurity should be  
3 clearly stated.  
4 Do you see that?  
5 A. Can you point me to where it  
6 is in the second paragraph which begins  
7 with, A rational?  
8 Q. Correct. Seven lines down.  
9 A. For impurities known to  
10 be -- okay.  
11 Q. That's what the document  
12 says, correct?  
13 A. For impurities known to be  
14 unusually potent or to produce toxic or  
15 unexpected pharmacological effects, the  
16 quantitation/detection limit of the  
17 analytical procedure should be  
18 commensurate with the level at which the  
19 impurities should be controlled.  
20 Yes, that's what it says.  
21 Q. Now, let's go to Page 10,  
22 which is Attachment 3, the decision tree  
23 for identification and qualification.  
24 You cited this in your

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1 report, right?  
2 A. Yes.  
3 Q. I'm just trying to find  
4 where you cited this.  
5 Do you know where this is in  
6 your report?  
7 A. No.  
8 Q. All right. Well, that's  
9 fine. I don't need to find it in your  
10 report.  
11 Do you see at the top --  
12 rephrase.  
13 Do you see at the top of the  
14 decision tree, the first input says, Is  
15 impurity greater than identification  
16 threshold?  
17 A. Yes.  
18 Q. And it says, No. And if you  
19 go to no, No action.  
20 And if, Yes, then you go  
21 down to the next question of structure  
22 identified.  
23 Do you see that?  
24 A. Yes.



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<p>1 Q. Do you see the little C next 2 to the word "threshold" up at the top? 3 A. Yes. 4 Q. Yep. And then on the next 5 page, let's go to the next page, Footnote 6 C says, Lower thresholds can be 7 appropriate if the impurity is unusually 8 toxic, correct? 9 A. Correct. 10 Q. So ZHP was required to know 11 that if it turned out that those peaks 12 that were below .1 percent represented 13 unusually toxic substances, like 14 N-nitroso compounds, that they couldn't 15 rely on the threshold of .1 percent; they 16 were required by cGMP to know that, 17 because that's what it said in the Q3A, 18 correct? 19 MS. DAVIDSON: Objection. 20 Mischaracterizes the document. 21 THE WITNESS: So if I go 22 back to the very first item that 23 you showed me in this set, in this 24 line of questioning, it says, For</p>	<p>1 issue, they're held to a higher standard 2 than an unusually less knowledgeable 3 manufacturer that doesn't figure it out 4 and doesn't realize, oh, there is this 5 potential impurity, they're held to a 6 lower standard? 7 Is that how it works? 8 MS. DAVIDSON: Objection. 9 BY MR. SLATER: 10 Q. It's a yes-or-no question. 11 I just want to know if the same standards 12 apply to everybody. 13 MS. DAVIDSON: I don't know 14 if that's another question, but if 15 it is, I'm objecting to that one, 16 too. 17 THE WITNESS: So, again, I 18 do not understand the basis of 19 your question or your assumption 20 of ZHP knew that these were potent 21 and toxic impurities. ZHP did not 22 know that. 23 When ZHP found that, when 24 ZHP understood that they had NDMA,</p>
Page 323	Page 325
<p>1 potential impurities that are 2 expected to be unusually potent, 3 for potential impurities that are 4 expected to be unusually potent. 5 If ZHP did not know that 6 that was a mutagenic impurity, how 7 would they conclude this is a 8 potent compound? 9 The same goes for the second 10 statement on Page 4, which says, 11 For impurities known to be 12 unusually potent or produce toxic 13 or unexpected effect. 14 Again, there is an 15 assumption in your questioning 16 that this unknown impurity was 17 potent. 18 BY MR. SLATER: 19 Q. Is the standard objective, 20 meaning we're going to hold all 21 manufacturers to a high standard, or is 22 it subjective, meaning, well, if this 23 manufacturer was really diligent and 24 figured out that there was a potential</p>	<p>1 they took all the right actions. 2 FDA didn't know in -- prior 3 to June 2018, prior to ZHP writing 4 to them and saying, hey, we have 5 NDMA present. FDA didn't know 6 that these unknown impurities in 7 valsartan which, according to FDA, 8 there were about 20 API 9 manufacturers, FDA didn't know 10 these were potent substances. 11 MR. SLATER: Let's go to the 12 next exhibit, which is the FDA 13 guidance for industry, Genotoxic 14 and Carcinogenic Impurities in 15 Drug Substances and Products, 16 Recommended Approaches, December 17 2008. Let's go to Exhibit-13. 18 - - - 19 (Whereupon, Exhibit 20 Afnan-13, No Bates, Guidance for 21 Industry Genotoxic and 22 Carcinogenic Impurities in Drug 23 Substances and Products: 24 Recommended Approaches, was marked</p>

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1 for identification.)  
 2 - - -  
 3 BY MR. SLATER:  
 4 Q. Have you ever seen this  
 5 document?  
 6 A. It's a draft document. It's  
 7 a draft which then eventually -- so, yes,  
 8 I have.  
 9 Q. Are you aware that ZHP cited  
 10 to this document in its DMFs as being  
 11 applicable to the manufacturing processes  
 12 for valsartan?  
 13 MS. DAVIDSON: Objection.  
 14 THE WITNESS: No, I'm not  
 15 aware that ZHP referenced this in  
 16 their DMF applications. I have  
 17 not come across that statement.  
 18 BY MR. SLATER:  
 19 Q. Did you consider this  
 20 guidance for industry and its contents in  
 21 forming your opinions in this case?  
 22 MS. DAVIDSON: Objection.  
 23 THE WITNESS: This is a  
 24 draft guidance, which is dated

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1 2008. It's an ICH guidance which  
 2 FDA had started working on, and,  
 3 therefore, it was in the various  
 4 stages.  
 5 This guidance later became a  
 6 final guidance.  
 7 BY MR. SLATER:  
 8 Q. Did you consider this  
 9 guidance in forming your opinions, this  
 10 document; yes or no?  
 11 MS. DAVIDSON: Objection.  
 12 THE WITNESS: I considered  
 13 --  
 14 BY MR. SLATER:  
 15 Q. So you did not consider this  
 16 document, correct?  
 17 A. This is a draft guidance  
 18 which is a precursor to M7.  
 19 Q. So is the answer, no, I did  
 20 not take this into account in forming my  
 21 opinions?  
 22 MS. DAVIDSON: Objection.  
 23 THE WITNESS: This is a  
 24 draft guidance dating back to

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1 2008.  
 2 In 2011, this was either  
 3 still a draft or not in process,  
 4 one.  
 5 As a draft guidance -- as a  
 6 fully approved guidance, if it was  
 7 an approved guidance, then it  
 8 would not be binding on FDA or  
 9 industry. That's stated on the  
 10 second or third page of every  
 11 guidance.  
 12 BY MR. SLATER:  
 13 Q. Let's go to the  
 14 introduction, Page 1.  
 15 It says, This guidance is  
 16 intended to inform pharmaceutical  
 17 manufacturers of the Food and Drug  
 18 Administration's current thinking  
 19 regarding genotoxic and carcinogenic  
 20 impurities in drug substances and drug  
 21 products, including biologic products,  
 22 that are regulated by the Center For Drug  
 23 Evaluation and Research. This guidance  
 24 provides recommendations on how to

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1 evaluate the safety of these impurities  
 2 during clinical development,  
 3 investigational new drug applications and  
 4 for marketing applications, new drug  
 5 applications, NDAs, biologics, license  
 6 applications, BLAs and abbreviated new  
 7 drug applications, ANDAs.  
 8 Do you see what I just read?  
 9 A. Yes.  
 10 Q. Do you know if ZHP was aware  
 11 of this document and felt that it was  
 12 obligated to comply with it?  
 13 MS. DAVIDSON: Objection.  
 14 BY MR. SLATER:  
 15 Q. Even though it said it's  
 16 non-binding, do you know what ZHP's  
 17 position on that was?  
 18 MS. DAVIDSON: Objection.  
 19 When you say "this document," do  
 20 you mean the draft or the final?  
 21 MR. SLATER: Yes. It's the  
 22 only document on the screen.  
 23 BY MR. SLATER:  
 24 Q. Do you know what ZHP's

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1 position was about this in their  
2 depositions; yes or no?  
3 A. It says, This draft  
4 guidance, when finalized. It was not  
5 final, one.  
6 Two, taking into account the  
7 same issue, if you look at the second  
8 paragraph, it says, This guidance is  
9 intended as an adjunct to the ICH  
10 guidance for industry, Q3A. I --  
11 Q. Are you refusing to answer  
12 my question?  
13 MS. DAVIDSON: Please don't  
14 interrupt him.  
15 MR. SLATER: You know what,  
16 Ms. Miller, I have to tell you  
17 something, you have an obligation,  
18 as an officer of the court, to  
19 know that your witness is not  
20 being responsive. This has gone  
21 on all day.  
22 I don't want to ask for more  
23 time, but he has sucked hours out  
24 of this deposition with these

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1 nonresponsive answers, objectively  
2 speaking. And I think that it  
3 would be in your interest as well,  
4 to just say give him direct  
5 answers to direct questions.  
6 It would help all of us.  
7 I'm not looking to come back  
8 again. I would really like to  
9 finish today.  
10 But if the witness refuses  
11 to answer simple questions, it's  
12 very frustrating and it frustrates  
13 the purpose of the deposition.  
14 BY MR. SLATER:  
15 Q. Do you know what ZHP's  
16 position is as to whether the FDA  
17 guidance that's on the screen applied to  
18 its development and manufacture of  
19 valsartan; yes or no?  
20 A. I have not looked at  
21 development reports from ZHP, so I cannot  
22 make any comments about that.  
23 This would have been  
24 applicable -- or the group that would

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1 have looked at development would have  
2 looked at the development in a different  
3 facility that I have not looked at,  
4 number one.  
5 Number two, whatever ZHP  
6 developed was submitted both to EDQM and  
7 to FDA. And both --  
8 Q. Go to the top of Page 2.  
9 MS. DAVIDSON: I'm sorry,  
10 Dr. Afnan, were you finished?  
11 THE WITNESS: I said -- no,  
12 I wasn't.  
13 I said and both EDQ and FDA  
14 accepted their application.  
15 BY MR. SLATER:  
16 Q. Look at the top of Page 2,  
17 it says, This guidance describes a  
18 variety of ways to characterize and  
19 reduce the potential lifetime cancer risk  
20 associated with patient exposure to  
21 genotoxic and carcinogenic impurities,  
22 both during clinical development and  
23 after approval.  
24 Do you see what I just read?

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1 A. Yes.  
2 Q. These approaches include,  
3 first bullet point, changing the  
4 synthetic and/or purification routes to  
5 minimize the formation and/or maximize  
6 the removal of the relevant impurity.  
7 Do you see that?  
8 A. Yes.  
9 Q. Number -- the second bullet  
10 point, Allowing a maximum daily exposure  
11 target of 1.5 micrograms per day for the  
12 relevant impurity as a general target for  
13 marketed products, though higher levels  
14 may be acceptable during clinical  
15 development. Certain impurities with  
16 structural alerts, suggesting  
17 particularly high genotoxic and  
18 carcinogenic potential, would not be  
19 appropriate for this general threshold  
20 approach and would need to be evaluated  
21 on a case-by-case basis.  
22 Do you see what I just read?  
23 A. Yes.  
24 Q. N-nitroso compounds fall

<p style="text-align: right;">Page 334</p> <p>1 within that category of impurities that 2 would not be appropriate for the 3 threshold approach, according to this 4 document; you understand that, correct? 5 MS. DAVIDSON: Objection. 6 THE WITNESS: I do. 7 However, at that time, 2008, 8 ZHP had no clue that their process 9 was making NDMA. 10 BY MR. SLATER: 11 Q. Let's go to the bottom of 12 the page where it says, Background. 13 The compounds that have been 14 demonstrated to induce genetic mutations, 15 chromosomal breaks and/or chromosomal 16 rearrangements are considered genotoxic 17 and have the potential to cause cancer in 18 humans. Exposures to even low levels of 19 these impurities may be of significant 20 concern. Therefore, the identification 21 limits provided in ICH Q3A and ICH Q3B 22 may not be acceptable for genotoxic or 23 carcinogenic impurities. 24 Do you see what I just read?</p>	<p style="text-align: right;">Page 336</p> <p>1 MS. DAVIDSON: Objection. 2 THE WITNESS: Yes. 3 BY MR. SLATER: 4 Q. Let's go to Page 6. 5 Section 3 is titled, 6 Recommended Approaches for Initial 7 Assessment of Genotoxic Potential of 8 Impurities. 9 Do you see that? 10 A. I do. 11 Q. The third paragraph under 12 that says, If an impurity that is present 13 at levels below the ICH qualification 14 thresholds is identified, the impurity 15 should be evaluated for genotoxicity and 16 carcinogenicity based on structural 17 activity relationship assessments, i.e., 18 whether there is a structural alert. 19 This evaluation can be conducted via 20 review of the available literature or 21 through a computational toxicology 22 assessment. Commonly used software 23 includes -- and they give examples of the 24 software.</p>
<p style="text-align: right;">Page 335</p> <p>1 A. Yes. 2 Q. Going a little further down, 3 about four lines further down, it says, 4 Although genotoxic and carcinogenic 5 properties can be acceptable for some 6 active pharmaceutical ingredients, APIs, 7 depending on clinical circumstances, for 8 example, cancer chemotherapies, 9 impurities in drug substances and drug 10 products generally do not have beneficial 11 effects and may impose a risk without 12 associated benefit. Therefore, 13 manufacturers should strive to achieve 14 the lowest levels of genotoxic or 15 carcinogenic impurities that are 16 technically feasible and/or levels that 17 convey no significant cancer risk. 18 Do you see what I just read? 19 A. Yes. 20 Q. And, again, the types of 21 impurities we're talking about would 22 include N-nitroso compounds, and that's 23 what they're talking about in this 24 guidance in 2008, correct?</p>	<p style="text-align: right;">Page 337</p> <p>1 Do you see what I just read? 2 A. Yes. 3 Q. And, again, if the impurity, 4 in this case NDMA from the zinc chloride 5 process, had been evaluated, it would 6 have been identified as NDMA and then ZHP 7 would have been duty bound to take action 8 to eliminate it from the valsartan and 9 not sell the valsartan with the NDMA, 10 correct? 11 MS. DAVIDSON: Objection. 12 BY MR. SLATER: 13 Q. I don't know what's so 14 funny, Doctor. 15 Can you just answer that 16 with a yes or no, please? 17 A. No, I can't answer with a 18 yes or no. 19 MS. DAVIDSON: Objection. 20 BY MR. SLATER: 21 Q. Fine. You can't answer with 22 a yes or no, I'll move to the next 23 question. 24 Let's go to Page 7.</p>

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1 Section 4 is titled,  
2 Recommended Approaches for Handling  
3 Genotoxic and Carcinogenic Impurities.  
4 And then Section A under  
5 that is titled, Prevention of Genotoxic  
6 and Carcinogenic Impurity Formation.  
7 Do you see that?  
8 A. Yes.  
9 Q. Prevention of genotoxic and  
10 carcinogenic impurity formation is  
11 important in drug manufacturing, correct?  
12 A. Yes.  
13 Q. You always want to prevent  
14 the formation of genotoxic and  
15 carcinogenic impurities when you're  
16 manufacturing drug substances, correct?  
17 MS. DAVIDSON: Objection.  
18 THE WITNESS: So, again,  
19 this guidance -- this draft  
20 guidance, which was published in  
21 2008, ZHP's process in 2007 was  
22 actually the TIN process.  
23 ZHP's process was  
24 investigated when they changed to

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1 the TEA and also when they changed  
2 to the zinc chloride process.  
3 And they looked, they  
4 assessed whether genotoxic  
5 impurities would be formed and  
6 they concluded that they're not  
7 present.  
8 They were going from an  
9 existing process, which was the  
10 TIN process, to the TEA process  
11 and then to the zinc chloride  
12 process. So what you're reading  
13 to me out of this draft guidance  
14 dated 2008 has an assumption that  
15 if a manufacturer knew that it  
16 has, effectively, carcinogenic  
17 substances in it, would they have  
18 an obligation to do what you say  
19 here? The answer is yes.  
20 However, ZHP investigated,  
21 assessed and decided that it  
22 didn't know. FDA vouches for that  
23 when FDA says, FDA nor industry  
24 knew about the formation, about

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1 the presence of these mutagenic  
2 substances.  
3 BY MR. SLATER:  
4 Q. Look now --  
5 MS. DAVIDSON: Can we --  
6 MR. SLATER: I'm right in  
7 the middle of this document. I'm  
8 not breaking while I'm going  
9 through this document. I'm sorry.  
10 BY MR. SLATER:  
11 Q. Looking now at Section A, it  
12 says, under the heading of, Prevention of  
13 Genotoxic and Carcinogenic Impurity  
14 Formation, Since drug-related impurities  
15 presumably provide limited, if any,  
16 therapeutic benefits and because of their  
17 potential to cause cancer in humans,  
18 every feasible technical effort should be  
19 made to prevent the formation of  
20 genotoxic or carcinogenic compounds  
21 during drug substance synthesis or drug  
22 product manufacturing.  
23 Do you see that?  
24 A. Yes.

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1 Q. Do you see what I just read?  
2 A. I do.  
3 Q. And you agree that ZHP  
4 needed to make every feasible technical  
5 effort to prevent the formation of  
6 genotoxic or carcinogenic compounds  
7 during the synthesis and manufacture of  
8 the valsartan it manufactured, correct?  
9 MS. DAVIDSON: Objection.  
10 THE WITNESS: If ZHP knew of  
11 the formation of genotoxic  
12 compounds, yes.  
13 This is not the case here.  
14 ZHP did not know about the  
15 formation of NDMA or NDEA in its  
16 valsartan process.  
17 BY MR. SLATER:  
18 Q. Let's flip over to the next  
19 page.  
20 MR. SLATER: Actually, no,  
21 no. Let's scroll down. Scroll  
22 down.  
23 BY MR. SLATER:  
24 Q. Do you see at the bottom of



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1 the page it says, under B1, the title is,  
2 Acceptable Levels to Support Marketing  
3 Applications.  
4 Do you see that?  
5 A. Yes.  
6 Q. And that's the thresholds  
7 that you've been talking about during the  
8 deposition, right?  
9 A. The threshold --  
10 MS. DAVIDSON: Objection.  
11 THE WITNESS: No. The  
12 threshold is based on, actually --  
13 this is the threshold for -- in  
14 this guidance, for very specific  
15 substances. The threshold is what  
16 is effectively detectable.  
17 So we're looking at two  
18 different things.  
19 You are making an assumption  
20 that every impurity is genotoxic  
21 in ZHP process and in ZHP product.  
22 That's not the case.  
23 ZHP assessed the process.  
24 ZHP shared that assessment with

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1 the regulators, that I do not have  
2 any mutagenic substances. ZHP  
3 received approval from the  
4 regulators that there were no  
5 mutagenic substances. FDA bears  
6 testimony, publicly, by saying  
7 neither the regulator nor the  
8 manufacturers knew about the  
9 formation of NDMA's nor about -- it  
10 calls them unexpected impurities.  
11 BY MR. SLATER:  
12 Q. And they issued a warning  
13 letter to ZHP -- and when they made all  
14 those statements that you just told me,  
15 in the statement from the FDA, they  
16 pointed out that they issued a warning  
17 letter to ZHP for its GMP violations that  
18 allowed these substances to exist in its  
19 valsartan; that's also what the FDA did,  
20 correct?  
21 MS. DAVIDSON: Objection.  
22 Misstates many, many things.  
23 THE WITNESS: No. FDA  
24 didn't do that.

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1 BY MR. SLATER:  
2 Q. Fine.  
3 A. FDA --  
4 Q. You said they didn't do it.  
5 Doctor, you answered my question.  
6 MS. DAVIDSON: No, no, Adam.  
7 If he has something to finish, you  
8 know that -- when you've had  
9 witnesses, you have them finish  
10 their answers, including  
11 Dr. Plunkett, who had very long  
12 answers.  
13 Dr. Afnan, complete your  
14 answer.  
15 THE WITNESS: FDA --  
16 MR. SLATER: Again, let me  
17 say for the record, you're telling  
18 your witness to ramble on  
19 non-responsively to keep sucking  
20 time out of the deposition, as an  
21 officer of the court.  
22 MS. DAVIDSON: No, that's  
23 not what I'm telling the witness.  
24 He's not my witness, first of all.

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1 He's an expert witness.  
2 MR. SLATER: Let him answer.  
3 Do you want --  
4 MS. DAVIDSON: He's in the  
5 middle of answering a question.  
6 You can't just cut him off, Adam,  
7 you know that. You know better  
8 than that.  
9 MR. SLATER: Thank you. I  
10 know better? You stand behind  
11 what's going on in this  
12 deposition? I find that hard to  
13 imagine, but I guess you do.  
14 BY MR. SLATER:  
15 Q. Do you have something else  
16 you want to say, Doctor, in response to  
17 my last question?  
18 A. Yes, I do.  
19 MS. DAVIDSON: He was in the  
20 middle of the answer.  
21 THE WITNESS: Yes, I do.  
22 MS. DAVIDSON: Do you even  
23 recall what you were talking  
24 about? Because I don't.

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1 MR. SLATER: Why are you  
2 saying that to him? Why would you  
3 suggest to him to say he doesn't  
4 remember? Why would you do that?  
5 It's inappropriate.

6 MS. DAVIDSON: I'm asking if  
7 he wants the question read back,  
8 Adam, because --

9 MR. SLATER: He doesn't  
10 need --

11 MS. DAVIDSON: -- all of  
12 your explosions make it impossible  
13 for me to even know where we were.  
14 Because you rudely interrupted  
15 him, then attacked me and then  
16 attacked the witness.

17 If he can -- if he  
18 remembers, great. I don't.

19 Go ahead, Dr. Afnan.

20 THE WITNESS: ZHP was issued  
21 a warning letter. The warning  
22 letter which effectively, as I  
23 have said, is informal and  
24 advisory, as per FDA. And that

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1 was issued because FDA needed more  
2 information on the conclusion of  
3 the investigation.

4 If you look at the  
5 communications after the warning  
6 letter between FDA and ZHP, FDA is  
7 as interested in the outcome of  
8 the warning letter -- of the  
9 investigation into the formation  
10 of NDMA's as is ZHP.

11 By that time, if -- you  
12 know, there is no product being  
13 manufactured, the process is  
14 changed -- or the process  
15 had stopped and the process was  
16 changed later.

17 So the warning letter is  
18 there as an informal iterative  
19 action by FDA to actually move the  
20 firm to come up with a conclusion  
21 of what the pathway for formation  
22 of these substances are.

23 FDA, at no point, states in  
24 the warning letter that ZHP has

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1 been making NDMA in its process  
2 since 2007 or '10 or '11 or  
3 whatever. It's not there.

4 MS. DAVIDSON: All right.  
5 Are we ready for a break? I think  
6 everybody needs a break.

7 MR. SLATER: No, I'm not  
8 done with this document, and I'm  
9 not breaking.

10 MS. DAVIDSON: I'm not  
11 familiar with the rule that you  
12 can go on with a document forever  
13 to prevent people from taking a  
14 break and going to the bathroom.

15 THE WITNESS: I am ready for  
16 a break.

17 MR. SLATER: You guys, if  
18 you want to stop, even though I'm  
19 asking you not to stop, I can't  
20 physically stop you.

21 So you tell me what you want  
22 to do. I'd like to continue. If  
23 you want to make me stop --

24 MS. DAVIDSON: Do you -- I

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1 would like to be cooperative.

2 Do you have more than five  
3 minutes left on this document?

4 MR. SLATER: I don't know,  
5 because every question I ask, I  
6 get a long, rambling nonresponsive  
7 speech. So I would say, yes, less  
8 than five minutes if I get  
9 responsive answers to questions.

10 MS. DAVIDSON: Adam, that's  
11 not necessary. If you have more  
12 than five --

13 MR. SLATER: Yes, it is.

14 MS. DAVIDSON: If you have  
15 more than five minutes on the  
16 document, I think we should take a  
17 break.

18 MR. SLATER: I don't. I  
19 don't have more than five minutes.

20 You just asked me. I don't  
21 have more than five minutes on the  
22 document. You can ask the expert  
23 that you hired whether or not he  
24 could answer questions with a

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1 direct answer. You're wasting my  
2 time on this video.  
3 MS. DAVIDSON: You're  
4 wasting it. So let's --  
5 MR. SLATER: What do you  
6 want to do, break or not break?  
7 Make a decision, please.  
8 MS. DAVIDSON: I would like  
9 to have a break and go to the  
10 ladies room.  
11 THE WITNESS: Yes, please.  
12 MR. SLATER: Off the record.  
13 VIDEO TECHNICIAN: We're off  
14 the record at 5:02 p.m.  
15 - - -  
16 (Whereupon, a brief recess  
17 was taken.)  
18 - - -  
19 VIDEO TECHNICIAN: We're  
20 back on the record at 5:07 p.m.  
21 BY MR. SLATER:  
22 Q. Looking at --  
23 MR. SLATER: Where is the  
24 document?

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1 BY MR. SLATER:  
2 Q. Looking at Section B1,  
3 titled, Acceptable Levels to Support  
4 Marketing Applications. Let's go to the  
5 carryover of that paragraph on the top of  
6 Page 8.  
7 And after they talk about  
8 various threshold levels, they state, at  
9 the end of that paragraph, at the top of  
10 the page, However, there are some  
11 compounds containing certain structural  
12 groups, aflatoxin-like, N-nitroso and  
13 azoxy structures, that have extremely  
14 high carcinogenic potency and are  
15 excluded from the threshold approach.  
16 Do you see that?  
17 A. Yes.  
18 Q. That includes NDMA and NDEA,  
19 correct?  
20 A. Yes.  
21 Q. So if FDA, in its guidance  
22 in 2008, said NDMA and NDEA are excluded  
23 from the threshold approach; that's what  
24 that means, correct?

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1 A. Yes.  
2 Q. Let's go to Page 13.  
3 Appendix A to this document  
4 is the decision tree flow diagram.  
5 Do you see that?  
6 A. Yes.  
7 Q. At the very top it says,  
8 Identify impurity.  
9 Do you see that?  
10 A. Yes.  
11 Q. That's the first thing the  
12 manufacturer is supposed to do, is  
13 actually make every feasible technical  
14 effort, as I read that language from  
15 earlier in the document, to identify the  
16 impurity, right?  
17 MS. DAVIDSON: Objection.  
18 THE WITNESS: Only if the  
19 expectation is for the impurity to  
20 be genotoxic.  
21 BY MR. SLATER:  
22 Q. It says, Once you identify  
23 the impurity, observed level exceeds --  
24 let me go back, actually, to what you

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1 just said.  
2 You're saying that you have  
3 to know that you have a genotoxic  
4 impurity before you have to look for the  
5 impurity and identify it?  
6 Isn't that a little  
7 circular, Doctor?  
8 MS. DAVIDSON: Objection.  
9 THE WITNESS: I don't think  
10 it is. I think what the  
11 requirements are, there has to be  
12 an expectation of genotoxic  
13 impurities; an expectation of  
14 genotoxic impurities.  
15 BY MR. SLATER:  
16 Q. What if you have an  
17 understanding of potential formation of  
18 genotoxic impurities, you don't expect it  
19 to be formed, but you know it might form  
20 from the process that you -- that you're  
21 using, are you able to say, well, we  
22 don't expect it, so we're not going to  
23 investigate why it's there, whether it's  
24 there or not? Is that acceptable?

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1 MS. DAVIDSON: Objection.  
2 MR. SLATER: Let me ask it  
3 again.  
4 BY MR. SLATER:  
5 Q. You say if it's expected.  
6 What if it's known to be  
7 possible, based on an understanding of  
8 the chemical process at issue? In that  
9 case, are you allowed to ignore  
10 identification of the impurity because  
11 you don't know for sure that it's been  
12 formed, or do you have to actually  
13 investigate to see if it's there?  
14 MS. DAVIDSON: Same  
15 objections.  
16 THE WITNESS: The answer is,  
17 if you expect it to be there, you  
18 need to identify it.  
19 In this case, ZHP did not  
20 know that it was potentially there  
21 or it could potentially be formed.  
22 BY MR. SLATER:  
23 Q. If ZHP knew that it could  
24 potentially form, they would have been

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1 required to test for the NDMA and NDEA,  
2 correct?  
3 A. If they expected it to be  
4 there, yes. But they did not know. This  
5 is not the case here.  
6 Q. Why do you keep changing my  
7 question? I did not ask about if they  
8 expected it.  
9 In fact, you didn't answer  
10 my prior question, Doctor, you evaded it.  
11 What you said -- I asked you  
12 a question, and I'll try it again.  
13 A. Okay.  
14 Q. If ZHP didn't expect NDMA to  
15 form but knew that it was potentially  
16 going to form based on an understanding  
17 of the chemical reactions, did ZHP have  
18 to test to see if NDMA was forming?  
19 A. It didn't expect it but  
20 potentially knew it would be there? To  
21 me, both those two are the same.  
22 If you expect it to be there  
23 or if you believe, potentially, it is  
24 going to be there, you will test for it.

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1 And, again, that's not what  
2 the case is here. ZHP didn't expect it  
3 nor did it know potentially it would be  
4 there.  
5 Q. Looking at the decision  
6 tree, this says, once you identify the  
7 impurity, you go to the next question,  
8 Whether the observed level exceeds the  
9 relevant ICH qualification threshold or  
10 is less than ICH qualification threshold  
11 but displays a structural alert.  
12 Do you see that?  
13 A. Yes.  
14 Q. So that's telling you, if  
15 you identified NDMA or NDEA, even if it  
16 was in a quantity less than the ICH  
17 qualification threshold, you would then  
18 have to go down where it says, yes, and  
19 determine, Are you able to prevent the  
20 formation of the impurity, correct?  
21 A. Yes. And, again, not the  
22 case here.  
23 Q. It's not the case here  
24 because ZHP did not evaluate the

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1 potential formation -- well, rephrase.  
2 It's not the case here  
3 because ZHP did not identify the  
4 potential for the formation of  
5 nitrosamines in its manufacturing  
6 process, correct? That's your opinion,  
7 right?  
8 A. Yes. ZHP looked at the  
9 process and did not predict or estimate  
10 or come up with a reason, justification  
11 for formation of mutagenic substances.  
12 Q. And the basis of your  
13 opinion that ZHP was not expected to  
14 identify the potential formation of NDMA  
15 or NDEA in these processes is your  
16 reliance on Dr. Xue for that point,  
17 correct?  
18 A. No, no, no.  
19 MS. DAVIDSON: Objection.  
20 BY MR. SLATER:  
21 Q. So you're now an organic  
22 chemistry expert again?  
23 A. No, no. I haven't answered  
24 yet.

<p>Page 358</p> <p>1 MS. DAVIDSON: And I haven't 2 even had a chance to -- to object, 3 because everybody is talking over 4 each other. 5 I object to that question. 6 It mischaracterizes his testimony. 7 Also, he started answering, 8 you did not let him finish. And 9 you, again, made a sarcastic 10 retort. Let him answer the 11 question. 12 THE WITNESS: I am not an 13 organic chemist. I am not 14 responding as an organic chemist, 15 I am not relying solely on 16 Dr. Xue's expertise in this case. 17 I am looking at what was 18 developed in the early phases in 19 2010, 2012, 2013, and submitted to 20 the regulators for their review 21 and approval. They did not 22 identify mutagenic substances 23 prior to 2018. 24 BY MR. SLATER:</p>	<p>Page 360</p> <p>1 organic chemistry, in terms of an 2 understanding of the literature and what 3 was available out there and what could 4 have been found and identified by organic 5 chemists, correct? 6 A. Your question had the word 7 "expected to." My response has been and 8 continues to be that ZHP looked at the 9 process and they came to the conclusion 10 that there are no mutagenic substances 11 formed in the process. 12 Furthermore, this was a 13 change to the TIN process, which went 14 from TIN to TEA and then it went to zinc 15 chloride. The time difference between 16 the TIN and the zinc chloride process was 17 three years. 18 There was a lot of studies 19 done during that time period, as well as 20 when they changed to TEA. So they did 21 investigate. They didn't see, they 22 didn't predict -- they didn't predict, 23 they didn't estimate, they did not come 24 up with that expectation of, oh, NDMA</p>
<p>Page 359</p> <p>1 Q. For your opinion that the 2 organic chemists at ZHP were not expected 3 to figure out that there was a potential 4 for the formation of NDMA or NDEA, do you 5 rely on Dr. Xue's opinion that it would 6 not be expected for a chemist to have 7 known or figured that out, or do you have 8 the opinion that the organic chemist did 9 not need to figure that out? 10 I'm trying to figure out 11 where your basis is to give this organic 12 chemistry opinion. 13 MS. DAVIDSON: Objection. 14 If that's a question. 15 THE WITNESS: I'm not -- 16 BY MR. SLATER: 17 Q. I'll ask it differently, 18 Doctor. 19 A. No, I -- 20 Q. The question of whether -- 21 the question of whether ZHP's chemists 22 were expected to identify the potential 23 formation of nitrosamines in these 24 manufacturing processes is a question of</p>	<p>Page 361</p> <p>1 will be formed here. 2 FDA also looked at the same 3 data, the same information, and the same 4 chemistry, and did not come up with a 5 conclusion of mutagenic substances are 6 formed in this process. 7 Q. Is that the basis for your 8 opinion that ZHP was not expected to 9 identify the potential formation of 10 nitrosamines? 11 What you just went through, 12 is that -- I'm just asking you, is that 13 the basis for the opinion? 14 MS. DAVIDSON: Objection. 15 BY MR. SLATER: 16 Q. I don't need you to repeat 17 it. 18 I just need to know, is that 19 the basis for the opinion? 20 A. That was not the opinion I 21 expressed. 22 Q. One of the reasons why you 23 say ZHP was not expected to identify the 24 potential formation of nitrosamines is</p>



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1 because ZHP did not identify the  
2 potential formation of the nitrosamines  
3 based on their risk assessment; is that  
4 one of the reasons why you give that  
5 opinion, because they didn't figure it  
6 out?

7 A. It's based on the risk  
8 assessment, as well as the research they  
9 have done.

10 Q. Another basis for your  
11 opinion is that the FDA didn't identify  
12 that risk of formation of nitrosamines.  
13 That's another reason why you say ZHP was  
14 not expected to identify that potential  
15 risk.

16 Do I understand that  
17 correctly?

18 A. I'm not using the FDA  
19 statement as a reason of saying that's  
20 because they didn't find it.

21 I'm saying, the FDA's  
22 statement verifies that they did not find  
23 it, they did not have an expectation of  
24 doing so.

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1 I'm not saying that ZHP  
2 based their decision on what the FDA had  
3 said, because the FDA said this in 2018.  
4 I'm saying the statements, two of, in  
5 2018 and 2019, were effectively verifying  
6 that ZHP had not looked at the process  
7 and said, you know, we expect NDMA's. FDA  
8 says, it was not expected to be there.

9 Q. In terms of your  
10 understanding that ZHP was not expected  
11 to have been able to identify the  
12 potential formation of nitrosamines, is  
13 there anything else that you're relying  
14 on besides what you just told me, those  
15 two points, for that opinion?

16 A. It's the investigation,  
17 which they had done, the assessments that  
18 they had done, the reports that they had  
19 issued, which effectively said, we've  
20 looked at the process and we do not  
21 expect any carcinogenic impurities.

22 The process -- this was a  
23 process revision, this was a process  
24 update -- or a process change.

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1 The original process was  
2 developed in 2007. Then, as they changed  
3 each step, they looked at the potentials  
4 of, you know, formation of undesired  
5 impurities, and their conclusion was that  
6 there is nothing there.

7 The analytical data  
8 supported that they were not finding  
9 anything or that there was no NDMA  
10 present.

11 Q. In forming the opinion --  
12 well, rephrase.

13 I don't need to go over it  
14 again.

15 MR. SLATER: Let's take this  
16 document down. And let's go to --  
17 back to the warning letter, okay.

18 I'm going to go back to the  
19 FDA warning letter. I think we  
20 used it. Yeah. We used it very  
21 early on.

22 THE WITNESS: Yes, we did.

23 MR. SLATER: It was  
24 Exhibit-2 or 3 or something?

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1 MS. DAVIDSON: Yeah, let's  
2 just make sure for the record we  
3 identify what the exhibit number  
4 is.

5 MR. SLATER: Exhibit-4.

6 MS. DAVIDSON: Thanks.

7 BY MR. SLATER:

8 Q. Let's go, in the warning  
9 letter, to Page 4.

10 This is what the FDA said in  
11 Section 2, the heading is, Failure to  
12 Evaluate the Potential Effect That  
13 Changes in the Manufacturing Process May  
14 Have on the Quality of Your API.

15 Do you see that heading?

16 A. Yes.

17 Q. The FDA states, In November  
18 2011, you approved the valsartan API  
19 process change that included the use of  
20 the solvent DMF. Your intention was to  
21 improve the manufacturing process,  
22 increase product yield and lower  
23 production costs. However, you failed to  
24 adequately assess the potential formation

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1 of mutagenic impurities when you  
2 implemented the new process.  
3 Specifically, you did not consider the  
4 potential for mutagenic or other toxic  
5 impurities to form from DMF degradants,  
6 including the primary DMF degradant  
7 dimethylamine. According to your ongoing  
8 investigation, dimethylamine is required  
9 for the probable human carcinogen NDMA to  
10 form during the valsartan API  
11 manufacturing process. NDMA was  
12 identified in valsartan API manufactured  
13 at your facility.  
14 Do you see what I just read?  
15 A. Yes.  
16 Q. So you agree the FDA found a  
17 violation of cGMP based on the failure to  
18 adequately assess the potential formation  
19 of mutagenic impurities when they  
20 implemented the new process.  
21 That's what it says on the  
22 document, correct?  
23 A. That's what it says on the  
24 document, which is written and issued

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1 with the benefit of hindsight.  
2 Q. The next paragraph says, You  
3 also failed to evaluate the need for  
4 additional analytical methods to ensure  
5 that unanticipated impurities were  
6 appropriately detected and controlled in  
7 your valsartan API before you approved  
8 the process change. You are responsible  
9 for developing and using suitable methods  
10 to detect impurities when developing and  
11 making change to your manufacturing  
12 processes. If new or higher levels of  
13 impurities are detected, you should fully  
14 evaluate the impurities and take action  
15 to ensure the drug is safe for patients.  
16 Do you see what I just read?  
17 A. Yes.  
18 Q. So the FDA found, again, a  
19 violation of cGMP because ZHP failed to  
20 apply analytical methods sufficient to  
21 identify these new impurities, and  
22 specifically NDMA -- NDMA and NDEA in  
23 their valsartan.  
24 That's what the words on the

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1 page say, correct?  
2 MS. DAVIDSON: Objection.  
3 Mischaracterizes the document.  
4 BY MR. SLATER:  
5 Q. It's what it says, right,  
6 Doctor?  
7 A. It says, You failed to  
8 evaluate the need for analytical -- for  
9 additional analytical methods.  
10 Again, it's important to  
11 look at the warning letter in the light  
12 of events that took place. When ZHP  
13 identified presence of NDMA, ZHP took  
14 action. They stopped manufacturing.  
15 They started investigating. They  
16 informed the FDA. They did a recall.  
17 They did all of those.  
18 So this, which is issued in  
19 November of 2018, is actually there to  
20 make sure that ZHP is going to keep its  
21 end of the bargain and continue its  
22 investigation.  
23 Otherwise, ZHP had stopped  
24 production, had stopped shipping, even

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1 before the import letter was put in  
2 place.  
3 Q. Going now to the third  
4 paragraph, the FDA states, Your response  
5 states that predicting NDMA formation  
6 during the valsartan manufacturing  
7 process required an extra dimension over  
8 current industry practice and that your  
9 process development study was adequate.  
10 We disagree. We remind you that common  
11 industry practice may not always be  
12 consistent with cGMP requirements and  
13 that you are responsible for the quality  
14 of drugs you produce.  
15 Do you see what I just read?  
16 A. Yes.  
17 Q. Did you read that when you  
18 wrote your opinion in your report?  
19 MS. DAVIDSON: Objection.  
20 THE WITNESS: Yes.  
21 BY MR. SLATER:  
22 Q. You keep saying to me, for  
23 the last however many hours we've been in  
24 this deposition, well, the FDA didn't

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1 find it, so there was no obligation for  
2 ZHP to find it.  
3 This warning letter from the  
4 FDA tells ZHP that it was their  
5 responsibility to identify the NDMA and  
6 they failed to do so.  
7 That's what the words on the  
8 page say, correct?  
9 A. Again, those are the words  
10 on the page. But it has to be taken in  
11 the context of what's going on. FDA had  
12 received, had shared every document that  
13 ZHP did. Every process that ZHP  
14 developed was shared with FDA. It was  
15 shared through the amendments to the DMF.  
16 It was also informed to FDA when the  
17 ANDAs were filed with FDA.  
18 So all of those were shared  
19 with FDA. This is in the -- with 20/20  
20 hindsight, in November of 2018, after FDA  
21 has been to site multiple times, has not  
22 found any issues with the quality system.  
23 Then a for-cause inspection, which  
24 results in this warning letter.

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1 So it has to be taken in the  
2 light of where it is, you know. It's --  
3 it's suddenly ZHP goes from being  
4 compliant to noncompliant on 29th of  
5 November 2018.  
6 Q. One of the things you've  
7 said to me multiple times is, well, this  
8 is with the benefit of hindsight, this is  
9 looking back with hindsight.  
10 You'd said that a few times  
11 to me, right?  
12 A. Yes.  
13 Q. Does the FDA have a warning  
14 letter that they also will issue in a  
15 different circumstance where they look  
16 into their crystal ball and see what  
17 someone is going to do in the future and  
18 give them a warning letter for future  
19 conduct that hasn't happened yet? Is  
20 there the crystal ball warning letter  
21 also?  
22 MS. DAVIDSON: Objection.  
23 THE WITNESS: Warning  
24 letters are issued after an

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1 inspection and after review of  
2 their response to the inspection.  
3 BY MR. SLATER:  
4 Q. Is it your -- rephrase.  
5 In forming your opinions,  
6 did you discount the significance of the  
7 retrospective analysis of what occurred,  
8 including that performed by ZHP and that  
9 performed by the FDA, because it was  
10 being done in hindsight?  
11 A. Sorry. Could you either  
12 rephrase or explain that question to me  
13 again?  
14 Q. Sure.  
15 In forming your opinions as  
16 to whether or not ZHP complied with  
17 cGMPs --  
18 A. Yes.  
19 Q. -- did you discount the  
20 significance of the FDA's findings in  
21 this warning letter and discount the  
22 significance of the findings by ZHP in  
23 its own deviation investigation reports  
24 because they were hindsight analyses

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1 looking back on what happened?  
2 MS. DAVIDSON: Objection.  
3 BY MR. SLATER:  
4 Q. I just want to know, yes or  
5 no, did you do that?  
6 MS. DAVIDSON: Okay. Again,  
7 every single time you ask a  
8 question I object and then you  
9 have your little colloquy.  
10 I'm objecting to the  
11 question, and if that follow up is  
12 a question, to that as well.  
13 THE WITNESS: So, again, you  
14 know, in June of 2018, when ZHP  
15 informed FDA about presence of  
16 NDMA, FDA did not issue,  
17 immediately, a warning letter and  
18 say, you know what, you're done,  
19 this is it, go back.  
20 FDA's warning letter is  
21 issued after the response. FDA  
22 issues this warning letter because  
23 the response was not as expected,  
24 the response to the 483.

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1 MR. SLATER: We're now going  
2 to put up on the screen  
3 Exhibit-14.  
4 - - -  
5 (Whereupon, Exhibit  
6 Afnan-14, ZHP00662283-2309,  
7 Investigation Regarding an Unknown  
8 Impurity (Genotoxic Impurity), was  
9 marked for identification.)  
10 - - -  
11 BY MR. SLATER:  
12 Q. This is a draft of the  
13 deviation investigation report, draft of  
14 Version 1.  
15 Do you see this on the  
16 screen? Have you seen this document  
17 before?  
18 A. I have seen the final  
19 version, yes.  
20 Q. All right. Well, let me go  
21 to -- let's go to -- the Bates number is  
22 308 at the bottom right.  
23 A. 308.  
24 Q. Under Section 5.2, it says,

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1 Control strategy. And the paragraph  
2 starts, Due to insufficient extent and  
3 depth of process research at the early  
4 stage, as well as insufficient study and  
5 understanding of potential genotoxic  
6 impurities, only side reaction product  
7 and degradation products were studied and  
8 was unaware of the further reaction  
9 between degradation products and raw  
10 material.  
11 Do you see what I just read?  
12 A. Yes.  
13 Q. Have you ever seen that  
14 before right now?  
15 A. As I said, this is the  
16 draft. I've seen the final version.  
17 Q. So you've never seen the  
18 language I just read to you, correct?  
19 A. I do not recall reading that  
20 language in the final version. But it  
21 may --  
22 Q. Now having seen that there  
23 were people at ZHP that wrote into a  
24 deviation investigation report that they

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1 had an insufficient extent and depth of  
2 process research and insufficient study  
3 and understanding of potential genotoxic  
4 impurities, and as a result, they failed  
5 to investigate and assess all of the  
6 reactions, now having seen that, that's  
7 an important fact that you need to take  
8 into consideration and reassess your  
9 opinions as to whether or not they did an  
10 adequate assessment of the risks of  
11 formation of nitrosamines, correct?  
12 MS. DAVIDSON: Objection.  
13 THE WITNESS: So this is a  
14 draft document. The purpose of a  
15 draft document is document in  
16 progress. It's being developed.  
17 So if you look at the final  
18 version, we will see what was  
19 there.  
20 A draft is something which  
21 is being written by people to be  
22 considered as a -- as a group, and  
23 an investigation. In pharma it's  
24 usually effectively reviewed

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1 collectively and it's also  
2 developed collectively.  
3 So because it was in the  
4 draft, it doesn't mean it's in the  
5 final version. It doesn't mean  
6 it's correct.  
7 I don't know who wrote that.  
8 I don't know whether the quality  
9 organization of the site agreed  
10 with that statement.  
11 BY MR. SLATER:  
12 Q. You agree with that  
13 statement, that that's what occurred?  
14 MS. DAVIDSON: Objection.  
15 THE WITNESS: This is a  
16 draft. Let's pull up the final  
17 version and look --  
18 BY MR. SLATER:  
19 Q. Let's answer my question.  
20 You just said I agree with  
21 that statement. You're saying you agree  
22 with the statement I just read to you,  
23 correct?  
24 MS. DAVIDSON: Objection.



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1 That mischaracterizes his  
2 testimony.  
3 MR. SLATER: Why are you  
4 testifying? Please don't.  
5 MS. DAVIDSON: He didn't say  
6 that.  
7 THE WITNESS: No, no.  
8 MS. DAVIDSON: You're  
9 misquoting him, Adam.  
10 MR. SLATER: Okay. Then  
11 I'll ask you the next question.  
12 BY MR. SLATER:  
13 Q. You did not say that.  
14 You know, one possibility is  
15 that that is true, that's what actually  
16 happened and someone at ZHP said, wait a  
17 second, we can't admit in this document,  
18 which we're submitting to the FDA, what  
19 this says, because it's an admission that  
20 we did insufficient research and an  
21 insufficient risk assessment, so we need  
22 to remove that. That's one possible  
23 reason why that language was removed.  
24 You'll -- as an objective

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1 expert, you would agree that's one  
2 possible explanation, right?  
3 MS. DAVIDSON: Objection.  
4 THE WITNESS: That's -- that  
5 would be against the GMPs of  
6 falsifying records. ZHP was not  
7 cited for data integrity and for  
8 falsifying records.  
9 BY MR. SLATER:  
10 Q. Did the FDA ever see this  
11 document that I'm showing you right now,  
12 this draft?  
13 MS. DAVIDSON: Objection.  
14 THE WITNESS: I have no  
15 idea. My point is not whether FDA  
16 saw this draft or not.  
17 FDA, if they had been  
18 presented with a draft, if the  
19 investigator would have normally  
20 said, give me the final version,  
21 not the draft.  
22 BY MR. SLATER:  
23 Q. If what's written there is  
24 actually true, ZHP violated cGMPs,

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1 correct?  
2 If what I just read to you  
3 is actually the truth, they violated  
4 cGMPs, correct?  
5 A. If what is written here --  
6 again, I go back, and you're not going to  
7 like my answer, that, effectively, that  
8 development work -- you know, assuming  
9 that's a correct statement, the depth of  
10 process of research at the early stages,  
11 as well as insufficient study and  
12 undertaking, would occur at the  
13 development location where GMPs do not  
14 apply.  
15 So, effectively, development  
16 is parceled -- is run at a different  
17 location to the -- to the manufacturing  
18 facility. That's why development has no  
19 GMPs, no -- no rules and regulations  
20 covering it. It's effectively best  
21 practices.  
22 Q. Pharmaceutical best  
23 practices?  
24 You said "best practices,"

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1 do you mean pharmaceutical best  
2 practices?  
3 A. It's the common practice  
4 that development is not regulated by any  
5 regulator.  
6 Q. The risk assessment --  
7 rephrase.  
8 If the statement I just read  
9 is a true statement in characterizing the  
10 level of research and understanding  
11 during the risk assessment phase of the  
12 change control process, which was  
13 governed by cGMP, then they violated  
14 cGMP, correct?  
15 A. If the level of research was  
16 insufficient, it is not contrary to GMPs,  
17 it is just a badly developed process.  
18 There are badly developed  
19 processes in pharma, in industry, which  
20 are there.  
21 Now, specifically if they  
22 are looking at, okay, we didn't do the  
23 research, or if the statement is a firm  
24 did not do their research to then find



1 the formation of degradants and  
2 degradation products and so on and so  
3 forth, and informed the regulator that I  
4 have done the work and everything is fine  
5 and it's not there, that would be -- in  
6 fact, not even GMPs, that would be lying  
7 to the regulator.

8 Q. The guidances we went  
9 through earlier talked about the need to  
10 take every feasible technical effort to  
11 avoid genotoxic impurities.

12 Remember we talked about  
13 that?

14 A. Yes.

15 Q. Part of taking every  
16 feasible technical effort would be making  
17 sure that you have sufficient extent and  
18 depth of process research and sufficient  
19 study and understanding of the potential  
20 genotoxic impurities so that you could  
21 understand the potential reactions and  
22 avoid those reactions and avoid the  
23 impurity, correct?

24 A. Yes. On the provision that

1 you expect to form undesirable  
2 impurities.

3 MR. SLATER: We can take  
4 that down.

5 Let's go -- can you get to  
6 Q7A by any chance? I'm sorry, I  
7 didn't give you a heads up, Chris.

8 Got it? Forget it? Here.  
9 You take it and when you find it  
10 let me know.

11 MS. DAVIDSON: Adam, do you  
12 want to go off the record while  
13 you figure this out?

14 MR. SLATER: Nope. I want  
15 to keep moving, one way or the  
16 other.

17 Hey, Chris, can you go to --  
18 put up the EMEA?

19 All right. Go off the  
20 record for a second. I got Chris  
21 all screwed up with this.

22 MS. DAVIDSON: No problem.

23 VIDEO TECHNICIAN: Hang on a  
24 second. We're off the record at

1 5:42 p.m.

2 - - -

3 (Whereupon, a brief recess  
4 was taken.)

5 - - -

6 VIDEO TECHNICIAN: We're  
7 back on the record at 5:42 p.m.

8 MR. SLATER: Let's put up  
9 Q7A. We're up to Exhibit-15 now.

10 - - -

11 (Whereupon, Exhibit  
12 Afnan-15, No Bates, Guidance for  
13 Industry Q7A Good Manufacturing  
14 Practice Guidance for Active  
15 Pharmaceutical Ingredients, was  
16 marked for identification.)

17 - - -

18 BY MR. SLATER:

19 Q. Looking at the Q7A, dated  
20 August 2001, that's a document you're  
21 familiar with, correct?

22 A. Yes.

23 Q. This applied, in your  
24 opinion, to ZHP's manufacture of

1 valsartan?

2 A. Yes.

3 Q. Let's go to Page 1.

4 Under the introduction, the  
5 second paragraph, the third line, it  
6 says, In this guidance, the term "should"  
7 identifies recommendations that, when  
8 followed, will ensure compliance with  
9 cGMPs. An alternative approach may be  
10 used if such approach satisfies the  
11 requirements of the applicable statutes.

12 Do you see what I just read?

13 A. Yes.

14 Can I ask a question? Is  
15 there a reason why you're using this  
16 version?

17 Q. Is there a different version  
18 you think I should be using?

19 A. I'm just asking because  
20 there is another one which was finalized  
21 in 2016.

22 Q. I thought I would use the  
23 one that was in effect the entire time.

24 A. Sure. Thank you.

<p style="text-align: right;">Page 386</p> <p>1 Q. Let's go to Page 28.</p> <p>2 Under the heading of,</p> <p>3 Laboratory Controls, if we go down to the</p> <p>4 third paragraph, it says, All</p> <p>5 specifications, sampling plans and test</p> <p>6 procedures should be scientifically sound</p> <p>7 and appropriate to ensure that raw</p> <p>8 materials, intermediates, APIs and labels</p> <p>9 and packaging materials conform to</p> <p>10 established standards of quality and/or</p> <p>11 purity.</p> <p>12 Do you see that?</p> <p>13 A. Yes.</p> <p>14 Q. And ZHP was required to</p> <p>15 ensure that all of its specifications,</p> <p>16 sampling plans and test procedures were</p> <p>17 scientifically sound, right?</p> <p>18 A. Yes.</p> <p>19 Q. That was a cGMP obligation,</p> <p>20 right?</p> <p>21 A. It is, yes.</p> <p>22 The reason I hesitate is</p> <p>23 because, actually, since this is a</p> <p>24 generic drug or generic API, there is a</p>	<p style="text-align: right;">Page 388</p> <p>1 triethylamine, right?</p> <p>2 MS. DAVIDSON: Objection.</p> <p>3 BY MR. SLATER:</p> <p>4 Q. Correct?</p> <p>5 A. If --</p> <p>6 MS. DAVIDSON: Objection.</p> <p>7 THE WITNESS: If ZHP wanted</p> <p>8 to sell its product to United</p> <p>9 States, it would have to meet the</p> <p>10 requirements of the USP monograph</p> <p>11 for valsartan.</p> <p>12 BY MR. SLATER:</p> <p>13 Q. And this language I just</p> <p>14 read, because, remember, we said should,</p> <p>15 we read that from the beginning, means if</p> <p>16 you do this, you're going to comply with</p> <p>17 cGMP.</p> <p>18 And they're saying here, you</p> <p>19 need to ensure that the raw materials,</p> <p>20 intermediates, APIs, et cetera, conform</p> <p>21 to established standards of quality</p> <p>22 and/or purity, right?</p> <p>23 MS. DAVIDSON: Objection.</p> <p>24 THE WITNESS: It says all</p>
<p style="text-align: right;">Page 387</p> <p>1 USP monograph of valsartan which would</p> <p>2 actually be the specifications for</p> <p>3 valsartan.</p> <p>4 Q. We went through, before,</p> <p>5 that the USP had explained that you must</p> <p>6 develop additional tests and analytical</p> <p>7 methods if you change the process and</p> <p>8 you're going to introduce external</p> <p>9 sources that could bring impurities into</p> <p>10 the process.</p> <p>11 Remember we went through</p> <p>12 that before?</p> <p>13 A. I do remember. That's not</p> <p>14 the one I'm referring to.</p> <p>15 There is a monograph for</p> <p>16 valsartan API.</p> <p>17 Q. I realize that.</p> <p>18 But the monograph for</p> <p>19 valsartan API is not the exhaustive list</p> <p>20 of tests and acceptance criteria</p> <p>21 applicable once ZHP developed its new</p> <p>22 processing methods and was introducing</p> <p>23 external sources that could bring</p> <p>24 impurities in, like DMF and</p>	<p style="text-align: right;">Page 389</p> <p>1 specifications, sampling plans,</p> <p>2 test procedures should be</p> <p>3 scientifically sound and</p> <p>4 appropriate to ensure that raw</p> <p>5 materials, intermediates, APIs and</p> <p>6 labels and packaging materials</p> <p>7 conform to standards.</p> <p>8 I'm not disputing that.</p> <p>9 BY MR. SLATER:</p> <p>10 Q. And in this case, it turned</p> <p>11 out that the -- that the valsartan</p> <p>12 contained NDMA, and, by definition, the</p> <p>13 established standards of quality and</p> <p>14 purity did not approve and allow for NDMA</p> <p>15 to be in valsartan, correct?</p> <p>16 MS. DAVIDSON: Objection.</p> <p>17 THE WITNESS: So, again, I</p> <p>18 would like to say that you're --</p> <p>19 so the monograph on valsartan does</p> <p>20 not have NDMA. You're correct, it</p> <p>21 doesn't have it in there.</p> <p>22 But it also stipulates what</p> <p>23 test methods should be used for --</p> <p>24 for assessing the specification,</p>

<p style="text-align: right;">Page 390</p> <p>1 the quality of valsartan.</p> <p>2 BY MR. SLATER:</p> <p>3 Q. We literally just went</p> <p>4 through this, that non-monograph tests</p> <p>5 and acceptance criteria are required</p> <p>6 where you change the processing methods</p> <p>7 or introduce external sources that could</p> <p>8 bring impurities to them, then you have</p> <p>9 to develop other testing and acceptance</p> <p>10 criteria to address those circumstances.</p> <p>11 That's literally what the</p> <p>12 USP says, right?</p> <p>13 MS. DAVIDSON: Objection.</p> <p>14 THE WITNESS: No. That's</p> <p>15 not what the USP says.</p> <p>16 It's if you believe that</p> <p>17 there are undesirable impurities</p> <p>18 present. Q3A allows you to have</p> <p>19 less than .1 percent.</p> <p>20 This document, which says</p> <p>21 that it should be scientifically</p> <p>22 sound, Q7, does not address about</p> <p>23 bringing in new test methods or</p> <p>24 whatever. Is --</p>	<p style="text-align: right;">Page 392</p> <p>1 what you're saying, is it?</p> <p>2 A. That's not what I'm saying,</p> <p>3 no.</p> <p>4 Q. Okay. And you would agree</p> <p>5 with me the USP did not permit NDMA or</p> <p>6 NDEA to be in the valsartan, correct?</p> <p>7 A. USP does not say in its</p> <p>8 monograph NDMA should be absent.</p> <p>9 Q. It's understood that there</p> <p>10 should be no NDMA or NDEA in valsartan in</p> <p>11 order to comply with USP, correct?</p> <p>12 A. It's understood and accepted</p> <p>13 that nitrosamines should not be present</p> <p>14 in drug product or drug substance at</p> <p>15 levels which cause concern.</p> <p>16 Q. Let's go to the next page,</p> <p>17 Page 29.</p> <p>18 Section B is, Testing of</p> <p>19 Intermediates and APIs. And the second</p> <p>20 paragraph says, An impurity profile</p> <p>21 describing the identified and</p> <p>22 unidentified impurities present in a</p> <p>23 typical batch produced by a specific</p> <p>24 controlled production process should</p>
<p style="text-align: right;">Page 391</p> <p>1 BY MR. SLATER:</p> <p>2 Q. I --</p> <p>3 MS. DAVIDSON: Are you</p> <p>4 interrupting him? Are you done?</p> <p>5 THE WITNESS: No, I'm not</p> <p>6 done.</p> <p>7 MS. DAVIDSON: You're both</p> <p>8 talking over each other.</p> <p>9 THE WITNESS: I'm not done.</p> <p>10 So Q7 specifically says,</p> <p>11 here are the specifications, ding,</p> <p>12 ding, ding, ding, specifications,</p> <p>13 sampling plans, test procedures</p> <p>14 should be scientifically sound and</p> <p>15 appropriate.</p> <p>16 And what I have said is the</p> <p>17 test procedures are defined by USP</p> <p>18 monograph of valsartan.</p> <p>19 BY MR. SLATER:</p> <p>20 Q. You're not testifying that</p> <p>21 the USP allows -- rephrase.</p> <p>22 You're not testifying the</p> <p>23 USP permitted the valsartan sold by ZHP</p> <p>24 to have NDMA or NDEA in it? That's not</p>	<p style="text-align: right;">Page 393</p> <p>1 normally be established for each API.</p> <p>2 The impurity profile should include the</p> <p>3 identity or some qualitative analytical</p> <p>4 designation, for example, retention time,</p> <p>5 the range of each impurity observed, and</p> <p>6 classification of each identified</p> <p>7 impurity, for example, inorganic,</p> <p>8 organic, solvent.</p> <p>9 Do you see that?</p> <p>10 A. Yes.</p> <p>11 Q. And that requirement applied</p> <p>12 to ZHP and required that they identify,</p> <p>13 in some manner as described here, every</p> <p>14 one of the impurities that were showing</p> <p>15 up on their testing, even if they hadn't</p> <p>16 identified exactly what the impurities</p> <p>17 are, correct?</p> <p>18 A. As per text, it says, An</p> <p>19 impurity profile describing the</p> <p>20 identified and unidentified impurities</p> <p>21 present in a typical batch produced by</p> <p>22 specific controls should normally be</p> <p>23 established for each API.</p> <p>24 So there should be a purity</p>

<p style="text-align: right;">Page 394</p> <p>1 and an impurity profile effectively 2 created for each product. And this was 3 done by ZHP. 4 Q. Where did ZHP develop an 5 impurity profile that identified the NDMA 6 and the NDEA in its valsartan in 7 accordance with this? Tell me where they 8 were identified -- and I'm going to use 9 the language, either identified by name 10 or some qualitative analytical 11 designation. 12 Tell me where that was done. 13 What document did that? 14 MS. DAVIDSON: Objection. 15 THE WITNESS: So if they had 16 identified NDMA, which they had 17 not, then it would not be listed 18 as an unknown -- unidentified 19 impurity. ZHP had no cause to 20 predict or estimate presence of 21 NDMA prior to June 2018. 22 ZHP did develop an impurity 23 profile and -- impurity profile in 24 2007, which was with the TIN</p>	<p style="text-align: right;">Page 396</p> <p>1 BY MR. SLATER: 2 Q. In fact, the NDMA and NDEA 3 were new impurities that were never 4 identified either by name or by some 5 qualitative analytical designation 6 anywhere in any document. 7 They never did that, right? 8 MS. DAVIDSON: Objection. 9 THE WITNESS: So ZHP, not 10 knowing that NDMA or NDEA is 11 present in the product, looked at 12 the impurity profile, and the 13 impurity profile effectively says 14 what do you have? 15 Again, going back to 3A, 16 Q3A, it says, you need to list 17 your known impurity profile, which 18 are listed in the USP monograph, 19 and then look at your impurity 20 profile and the collective sum of 21 those cannot go above a certain 22 limit. 23 So they looked at it; it was 24 not there. They didn't see it.</p>
<p style="text-align: right;">Page 395</p> <p>1 process. Then as they did each 2 change, this question was raised, 3 addressed and verified that the 4 impurity profile has not 5 drastically changed, drastically 6 changed meaning some -- you know, 7 effectively, impurity A 8 concentration had gone down as 9 they improved the process. The 10 impurity profile, it stated, did 11 not change. 12 So both the impurity profile 13 and the purity profile remained 14 unchanged as they went from the 15 TEA process to the zinc chloride 16 process. 17 BY MR. SLATER: 18 Q. ZHP specifically said that 19 the impurity profile had not changed and 20 they said that in the DMF for both of the 21 new processes, right? 22 A. Correct. 23 MS. DAVIDSON: Objection. 24 THE WITNESS: Sorry.</p>	<p style="text-align: right;">Page 397</p> <p>1 They did not know about NDMA or 2 NDEA. 3 BY MR. SLATER: 4 Q. The peaks -- we'll talk 5 about NDMA. 6 The peak for NDMA was there, 7 they just didn't identify what it was. 8 We've agreed to that before, 9 right? You've told me it was too small, 10 whatever. But -- let me rephrase. 11 The NDMA peak was there, it 12 just wasn't identified, and it wasn't 13 identified by name, and it wasn't 14 identified by qualitative analytical 15 designation as described in this ICH 16 guidance; it was never identified, 17 correct? 18 MS. DAVIDSON: Objection. 19 BY MR. SLATER: 20 Q. Either by name or by 21 location or anything else? 22 MS. DAVIDSON: Objection. 23 That was a lot of questions. 24 BY MR. SLATER:</p>

<p style="text-align: right;">Page 398</p> <p>1 Q. I'll ask it again, because I</p> <p>2 know you got a great objection there.</p> <p>3 Let's go back to my original</p> <p>4 question.</p> <p>5 Where did ZHP identify the</p> <p>6 NDMA and NDEA, either by identity or</p> <p>7 qualitative analytical designation, as</p> <p>8 required in what I just read?</p> <p>9 A. ZHP --</p> <p>10 Q. I've never seen the</p> <p>11 document. Is there a document where that</p> <p>12 happened?</p> <p>13 MS. DAVIDSON: Adam,</p> <p>14 literally, he started talking and</p> <p>15 you asked another question.</p> <p>16 What are you doing?</p> <p>17 MR. SLATER: I'm trying to</p> <p>18 get him to actually answer my</p> <p>19 question.</p> <p>20 BY MR. SLATER:</p> <p>21 Q. I'm asking if there's a</p> <p>22 document.</p> <p>23 MR. SLATER: Why don't you</p> <p>24 please ask your witness to just</p>	<p style="text-align: right;">Page 400</p> <p>1 after it had been investigated.</p> <p>2 They did not report it to</p> <p>3 clients unless the clients asked. And</p> <p>4 when they did their assessment, which was</p> <p>5 based on GC FID and GCMS pointed to a</p> <p>6 solvent or solvents that they were using</p> <p>7 in the process, not DMF, not any of the</p> <p>8 DMF degradants. There are other</p> <p>9 processes.</p> <p>10 And that is in the</p> <p>11 communications which went between the</p> <p>12 clients and ZHP saying, what was that</p> <p>13 impurity?</p> <p>14 That was also the subject of</p> <p>15 my call with Jucai Ge.</p> <p>16 Q. Nowhere in any impurity</p> <p>17 profile have you seen where ZHP</p> <p>18 specifically identified each impurity</p> <p>19 observed and classified each identified</p> <p>20 impurity as required here? That did not</p> <p>21 happen, right?</p> <p>22 MS. DAVIDSON: Objection.</p> <p>23 THE WITNESS: I've answered</p> <p>24 the question. And I'll answer</p>
<p style="text-align: right;">Page 399</p> <p>1 tell me, yes or no, is there a</p> <p>2 document where he's seen that.</p> <p>3 It's the only question I'm asking.</p> <p>4 THE WITNESS: There was --</p> <p>5 MS. DAVIDSON: I'm objecting</p> <p>6 to this colloquy.</p> <p>7 Ali, if you know what</p> <p>8 question is pending, go ahead and</p> <p>9 answer.</p> <p>10 THE WITNESS: There are</p> <p>11 three or four questions there.</p> <p>12 BY MR. SLATER:</p> <p>13 Q. I'll ask it again, because</p> <p>14 you're confused, you think there's three</p> <p>15 or four questions.</p> <p>16 Is there a document you can</p> <p>17 point me to where ZHP identified, either</p> <p>18 by name or by qualitative analytical</p> <p>19 designation, the NDEA and the NDMA; yes</p> <p>20 or no?</p> <p>21 A. ZHP was not aware of NDMA or</p> <p>22 NDEA until June 2018. Prior to June</p> <p>23 2018, ZHP had looked at the impurity</p> <p>24 profile and the peaks coming, alluding,</p>	<p style="text-align: right;">Page 401</p> <p>1 again.</p> <p>2 ZHP did not know about NDMA</p> <p>3 or NDEA until June 2018. ZHP had</p> <p>4 looked at the impurity profile,</p> <p>5 and the impurity profile, which</p> <p>6 would have been filed with the DMF</p> <p>7 changes, would have said what was</p> <p>8 there and the fact that the</p> <p>9 profile was whatever it was.</p> <p>10 BY MR. SLATER:</p> <p>11 Q. And we both know from</p> <p>12 reading the DMF that that impurity</p> <p>13 profile did not mention NDMA or NDEA or</p> <p>14 identify either of those impurities in a</p> <p>15 qualitative or quantitative way.</p> <p>16 They were not mentioned at</p> <p>17 all, correct?</p> <p>18 A. I'll give a repeat.</p> <p>19 MS. DAVIDSON: Objection.</p> <p>20 THE WITNESS: ZHP didn't</p> <p>21 know about NDMA or NDEA in its</p> <p>22 valsartan process until June 2018.</p> <p>23 So if it didn't know about the</p> <p>24 presence of NDMA or NDEA there was</p>



1 no way for it to actually list  
2 them as saying, here is NDMA or  
3 NDEA.

4 It was not expected, it was  
5 not detected, the methods that  
6 were there were not sufficient to  
7 detect them. FDA also agrees with  
8 that statement.

9 MR. SLATER: You can take  
10 that document down.

11 BY MR. SLATER:

12 Q. You talked about  
13 bioequivalence a lot in your report.

14 Do you know what that means?

15 A. I hope so.

16 Q. What does bioequivalence  
17 mean?

18 A. It means it will have the  
19 same response biologically as the  
20 reference listed drug.

21 Q. So, for example, with  
22 valsartan, in simple terms, it will still  
23 have the desired effect on the body to  
24 control blood pressure?

1 A. The same desired effect as  
2 its reference listed drug, yes.

3 Q. Therapeutic equivalent is a  
4 different term with a different meaning,  
5 correct?

6 A. Yes.

7 Q. That means that the drug has  
8 the same quality, identity, and purity as  
9 the reference listed drug, correct?

10 MS. DAVIDSON: Did I freeze  
11 or did Adam freeze?

12 THE WITNESS: No, you're not  
13 frozen.

14 BY MR. SLATER:

15 Q. Correct?

16 MS. DAVIDSON: I'm sorry,  
17 I'm not sure what happened.

18 Did you say something after  
19 the word "identity"?

20 MR. SLATER: I'll just ask  
21 the question again.

22 MS. DAVIDSON: Okay. I'm  
23 sorry. I didn't force my Internet  
24 to stop.

1 MR. SLATER: Can I just  
2 talk, please?

3 MS. DAVIDSON: Sure.

4 BY MR. SLATER:

5 Q. Therapeutic equivalent means  
6 the drug has the same quality, identity  
7 and purity as the reference listed drug,  
8 correct?

9 A. Yes.

10 Q. And you understand that our  
11 claim in this case is not that there was  
12 a lack of bioequivalence, you understand  
13 that the claim is that there was a lack  
14 of therapeutic equivalence?

15 You understand that, right?

16 MS. DAVIDSON: Objection.

17 BY MR. SLATER:

18 Q. Or do you not understand  
19 that?

20 MS. DAVIDSON: Objection.

21 THE WITNESS: That's -- I  
22 understand what therapeutic  
23 equivalence is. I think the  
24 question of same quality -- the

1 quality, as I said earlier,  
2 according to USP, is defined to be  
3 98 to 102 percent purity for  
4 valsartan.

5 So that's what it means to  
6 me, 98 to 102 percent.

7 BY MR. SLATER:

8 Q. With all due respect, all  
9 I'm asking you is this: You used the  
10 term "bioequivalence," and you said the  
11 plaintiffs' experts are criticizing the  
12 lack of bioequivalence. You said that  
13 many times in your report.

14 Do you understand that the  
15 claim is not a lack of bioequivalence but  
16 actually is a claim of a lack of  
17 therapeutic equivalence?

18 I'm just asking if you  
19 understand that.

20 MS. DAVIDSON: Objection.

21 THE WITNESS: So your -- the  
22 plaintiff experts referred to  
23 bioequivalence. That's what I  
24 have addressed.

1 You're muted.  
 2 MR. SLATER: Can I have the  
 3 court reporter read back the  
 4 answer, please? I lost the feed  
 5 for a second.  
 6 - - -  
 7 (Whereupon, the court  
 8 reporter read the following part  
 9 of the record:  
 10 "Answer: The plaintiff  
 11 experts referred to  
 12 bioequivalence. That's what I  
 13 have addressed.")  
 14 - - -  
 15 BY MR. SLATER:  
 16 Q. You talked in your report  
 17 about Valisure and testing of Diovan,  
 18 right?  
 19 A. I did, yes.  
 20 Q. Are you relying on  
 21 Valisure's testing of Diovan as a basis  
 22 for your opinions in this case?  
 23 A. Could you just repeat the  
 24 first part? Am I --

1 Q. Are you relying on  
 2 Valisure's purported findings on testing  
 3 of Diovan as a basis for your opinions in  
 4 this case?  
 5 A. So Diovan -- Valisure tested  
 6 a Novartis product. Novartis in United  
 7 States. That product was the only -- the  
 8 only valsartan which is approved by --  
 9 approved for Novartis is an NDA drug,  
 10 which is listed as a reference standard  
 11 and as the ROD.  
 12 Valisure tested Novartis  
 13 product. There is no expectation for  
 14 this to be a generic sample which it  
 15 brought to the U.S. and to be tested.  
 16 Valisure tested it, and the plaintiff  
 17 expert lab, Emory, Dr. Najafi, he also  
 18 verified those tests.  
 19 Now, I believe -- I am not  
 20 certain, but I believe that that Diovan  
 21 was -- or those samples were Diovan.  
 22 I've asked Skadden counsel for the NDC  
 23 number, which has been requested but not  
 24 yet provided.

1 If we have the NDC number,  
 2 that would directly pinpoint to whether  
 3 it's Diovan or not.  
 4 Q. I'll let you assume, for  
 5 purposes of these next questions, that  
 6 what Valisure tested was Diovan, okay?  
 7 A. Okay.  
 8 Q. If that's the case, are you  
 9 relying on Valisure's testing of Diovan  
 10 purportedly finding NDMA as a basis for  
 11 your opinions? Is it something you're  
 12 relying on as one of the bases for your  
 13 opinions?  
 14 MS. DAVIDSON: Objection.  
 15 THE WITNESS: Which opinion?  
 16 BY MR. SLATER:  
 17 Q. Any of your opinions.  
 18 MS. DAVIDSON: The first  
 19 question --  
 20 BY MR. SLATER:  
 21 Q. This is really not that  
 22 complicated. I'm not asking for an  
 23 explanation or which opinions. It's a  
 24 very simple question.

1 Are you relying on  
 2 Valisure's testing of Diovan and  
 3 purported finding of NDMA in Diovan as  
 4 one of the bases for your opinions in  
 5 this case; yes or no?  
 6 MS. DAVIDSON: Well, first  
 7 you said assume something. Is the  
 8 assumption still part of your  
 9 question?  
 10 MR. SLATER: Yes. That they  
 11 tested Diovan.  
 12 THE WITNESS: So there are  
 13 212 opinions that I have put in.  
 14 I really would need to be very  
 15 careful of saying this applies  
 16 across the board, because, you  
 17 know, some of them have nothing to  
 18 do with Valisure testing. My --  
 19 BY MR. SLATER:  
 20 Q. I'll ask you a different  
 21 question.  
 22 MS. DAVIDSON: Wait. He was  
 23 in the middle of talking.  
 24 MR. SLATER: Are you just --

<p style="text-align: right;">Page 410</p> <p>1 I'm trying to use time wisely</p> <p>2 here, and you're just wanting to</p> <p>3 just keep talking on something</p> <p>4 like this. I mean, what's the</p> <p>5 point?</p> <p>6 MS. DAVIDSON: You can't</p> <p>7 interrupt a witness. It's, like,</p> <p>8 Rule 101.</p> <p>9 MR. SLATER: Maybe you</p> <p>10 should interrupt him.</p> <p>11 BY MR. SLATER:</p> <p>12 Q. Keep going, Doctor.</p> <p>13 A. So my point is that</p> <p>14 Valisure -- you know, the plaintiff</p> <p>15 experts make the statement saying this</p> <p>16 drug is not equivalent to Diovan.</p> <p>17 The point is, if Diovan has</p> <p>18 NDMA in it, then what are we talking</p> <p>19 about? Because -- because even Diovan,</p> <p>20 if it had NDMA in it, then you don't --</p> <p>21 that's a discovery which is made late in</p> <p>22 the day.</p> <p>23 Q. Did you read Dr. Xue's</p> <p>24 deposition?</p>	<p style="text-align: right;">Page 412</p> <p>1 that's significant to you because if</p> <p>2 Diovan had NDMA in it, you said, what are</p> <p>3 we talking about? Do I understand you</p> <p>4 correctly?</p> <p>5 A. No. My point --</p> <p>6 Q. Fine. That's fine. I don't</p> <p>7 understand you. Next question.</p> <p>8 Do you have any</p> <p>9 understanding or assumption that the</p> <p>10 testing that was performed by Valisure</p> <p>11 was reliable?</p> <p>12 A. It was verified by the</p> <p>13 plaintiff expert's lab.</p> <p>14 Q. You're assuming that</p> <p>15 Dr. Najafi's lab actually verified the</p> <p>16 testing of the Diovan that's referred to</p> <p>17 by Valisure; yes or no?</p> <p>18 A. Dr. Najafi tested the same</p> <p>19 samples, and according to his deposition,</p> <p>20 he said that -- first he said, yes, they</p> <p>21 were the same, and then he said they were</p> <p>22 in the same ballpark.</p> <p>23 So, no he didn't test for</p> <p>24 Valisure. The results issued or reported</p>
<p style="text-align: right;">Page 411</p> <p>1 A. I did read Dr. Xue's</p> <p>2 deposition.</p> <p>3 Q. Do you agree with me --</p> <p>4 well, rephrase.</p> <p>5 Do you agree with Dr. Xue</p> <p>6 that the chemical -- rephrase.</p> <p>7 Do you agree with Dr. Xue</p> <p>8 that the manufacturing process and the</p> <p>9 chemical reactions in the TIN process</p> <p>10 which is used to make Diovan is not</p> <p>11 capable of forming NDMA?</p> <p>12 MS. DAVIDSON: Objection.</p> <p>13 THE WITNESS: Can I see that</p> <p>14 statement from Dr. Xue, please?</p> <p>15 BY MR. SLATER:</p> <p>16 Q. No, I don't have time to</p> <p>17 start showing you things. So let me ask</p> <p>18 the question differently.</p> <p>19 Do you assume, in forming --</p> <p>20 rephrase.</p> <p>21 If the -- rephrase.</p> <p>22 If Valisure tested Diovan,</p> <p>23 and if Valisure reported that they found</p> <p>24 NDMA based on that testing, you're saying</p>	<p style="text-align: right;">Page 413</p> <p>1 on Valisure are not necessarily done by</p> <p>2 Emory Labs. But Emory Labs tested and</p> <p>3 agreed with those, according to</p> <p>4 Dr. Najafi.</p> <p>5 Q. Are you aware that the</p> <p>6 samples that were provided to Dr. Najafi,</p> <p>7 that the results he reported, don't match</p> <p>8 up to the results for the Diovan that was</p> <p>9 tested by Valisure, which shows that he</p> <p>10 actually tested different blind</p> <p>11 specimens?</p> <p>12 Did you ever look at that</p> <p>13 and match that up?</p> <p>14 MS. DAVIDSON: Objection.</p> <p>15 BY MR. SLATER:</p> <p>16 Q. I'm just asking, did you</p> <p>17 ever look at the results to see that they</p> <p>18 are different?</p> <p>19 A. His deposition said that</p> <p>20 Valisure told him he is in the right</p> <p>21 ballpark.</p> <p>22 Q. Did you ever see the letter</p> <p>23 from FDA to Valisure dated December 5,</p> <p>24 2022?</p>

1 A. Yes.

2 Q. Did you see all of the  
3 different problems that the FDA  
4 identified with Valisure's testing,  
5 including their testing for nitrosamine  
6 impurities in valsartan?

7 A. I do -- I prefer -- I would  
8 appreciate if you could show it to me.

9 Q. I'm just asking, do you  
10 remember seeing that the FDA criticized  
11 Valisure's testing for nitrosamine  
12 impurities in valsartan?

13 MS. DAVIDSON: Objection.

14 THE WITNESS: I really would  
15 like to see the document before I  
16 agree to you.

17 BY MR. SLATER:

18 Q. Do you have an opinion that  
19 Valisure's testing was reliable and that  
20 you're relying on what they say about  
21 what they found in Diovan?

22 Just yes or no, I just want  
23 to know.

24 MS. DAVIDSON: Objection.

1 He responded multiple times. He  
2 said he wanted to see the letter.  
3 You're badgering him and  
4 pressuring him.

5 MR. SLATER: No. What I'm  
6 doing is not getting all my time  
7 sucked up to show him something  
8 that he already knows.

9 THE WITNESS: I have not  
10 looked at Valisure's document --

11 BY MR. SLATER:

12 Q. Okay. I'll --

13 A. No, no, no.

14 I have not looked at  
15 Valisure's GMP systems to make a decision  
16 whether it's reliable or not.

17 Q. Okay.

18 A. Sorry.

19 MS. DAVIDSON: If you want  
20 him to look at the letter --

21 MR. SLATER: No, I really  
22 don't. I'm going to ask my next  
23 question.

24 MS. DAVIDSON: -- off the

1 record. Please don't interrupt  
2 me.

3 I was saying if you want --  
4 I was trying to be gracious.

5 MR. SLATER: It's okay.  
6 We're way past gracious, I'm  
7 sorry. I just need to ask my next  
8 question.

9 I don't know why you're  
10 making a face. I just want --

11 MS. DAVIDSON: I just think  
12 it's incredibly rude, Adam, how  
13 you talk over me. Incredibly rude  
14 and shocking.

15 MR. SLATER: I'm sorry, I  
16 don't have a lot of time.

17 MS. DAVIDSON: While I was  
18 offering to go off so that you  
19 wouldn't use your time in looking  
20 at the document.

21 MR. SLATER: I don't need to  
22 look at the document.

23 BY MR. SLATER:

24 Q. Doctor, does the approved

1 formulation of Diovan include NDMA in it?

2 A. Approved formulation? Can  
3 you be very specific?

4 Do you mean what FDA  
5 approved or do you mean what is being  
6 sold in the market?

7 Q. What FDA approved.

8 A. So what FDA approved should  
9 not have -- actually, I have no idea,  
10 because now it's hindsight. We are  
11 looking back.

12 At the time FDA approved,  
13 FDA assumed there was no NDMA. At the  
14 time FDA approved ZHP process, there was  
15 an understanding that there was no NDMA.

16 Q. If there would be NDMA in a  
17 Diovan pill, that would be due to a cGMP  
18 violation in the manufacturing process,  
19 correct?

20 MS. DAVIDSON: Objection.  
21 Calls for speculation.

22 THE WITNESS: I can't make  
23 that statement. You know, you  
24 want a yes-or-no answer, and I'm

<p style="text-align: right;">Page 418</p> <p>1       sorry, I can't give you a</p> <p>2       yes-or-no answer.</p> <p>3       BY MR. SLATER:</p> <p>4       Q.   Are you aware that the</p> <p>5       manufacturing process and chemical</p> <p>6       reactions for Diovan are incapable of</p> <p>7       forming NDMA as an impurity?</p> <p>8       MS. DAVIDSON: Objection.</p> <p>9       THE WITNESS: I have not</p> <p>10      looked at the NDMA process. I am</p> <p>11      looking at Valisure. I am looking</p> <p>12      at, effectively, Dr. Najafi saying</p> <p>13      that, yes, he found it and it's in</p> <p>14      the -- ballpark agrees with</p> <p>15      Valisure's data.</p> <p>16      BY MR. SLATER:</p> <p>17      Q.   If I'm correct and Dr. Xue</p> <p>18      is correct that the manufacturing process</p> <p>19      for Diovan was not capable of creating</p> <p>20      NDMA, then the only way for NDMA to get</p> <p>21      into the pills would be due to a cGMP</p> <p>22      violation, correct?</p> <p>23      A.   I cannot --</p> <p>24      MS. DAVIDSON: Same</p>	<p style="text-align: right;">Page 420</p> <p>1       BY MR. SLATER:</p> <p>2       Q.   We've put on the screen</p> <p>3       Exhibit-16, a genotoxicity statement,</p> <p>4       dated July 14, 2015, signed by Lucy Liu,</p> <p>5       manager of regulatory affairs at ZHP.</p> <p>6       Have you seen this document?</p> <p>7       A.   I think I have.</p> <p>8       Q.   And you can see on July 14,</p> <p>9       2015, ZHP represented that its valsartan</p> <p>10      was, to the best of its knowledge, in</p> <p>11      accordance with the guideline, the</p> <p>12      EMA/CHMP/QWP/251344/2006 and ICH M7.</p> <p>13      Do you see that?</p> <p>14      A.   Yes.</p> <p>15      Q.   Do you know what the first</p> <p>16      guideline is that they listed there?</p> <p>17      A.   It's the quality working</p> <p>18      party of EMA.</p> <p>19      Q.   What's the significance of</p> <p>20      that guideline?</p> <p>21      A.   That --</p> <p>22      MS. DAVIDSON: Objection.</p> <p>23      THE WITNESS: Yes.</p> <p>24      So can we pull it up,</p>
<p style="text-align: right;">Page 419</p> <p>1       objections.</p> <p>2       THE WITNESS: I cannot</p> <p>3       comment on Novartis's</p> <p>4       manufacturing process because I</p> <p>5       have not looked at it. I don't</p> <p>6       know what they do.</p> <p>7       You obviously have knowledge</p> <p>8       of the process. I don't.</p> <p>9       MR. SLATER: Let's go off</p> <p>10      the record.</p> <p>11      VIDEO TECHNICIAN: We're off</p> <p>12      the record at 6:14 p.m.</p> <p>13      - - -</p> <p>14      (Whereupon, a brief recess</p> <p>15      was taken.)</p> <p>16      - - -</p> <p>17      VIDEO TECHNICIAN: We're</p> <p>18      back on the record at 6:22 p.m.</p> <p>19      - - -</p> <p>20      (Whereupon, Exhibit</p> <p>21      Afnan-16, ZHP01721348,</p> <p>22      Genotoxicity Statement, was marked</p> <p>23      for identification.)</p> <p>24      - - -</p>	<p style="text-align: right;">Page 421</p> <p>1       please?</p> <p>2       BY MR. SLATER:</p> <p>3       Q.   I don't have that. I've</p> <p>4       never seen it. I don't even know what it</p> <p>5       is.</p> <p>6       A.   Okay. So this is EMA.</p> <p>7       This is very old, because they are no</p> <p>8       longer called EMA.</p> <p>9       And what they did was they</p> <p>10      actually, I think, and I'm not sure, so</p> <p>11      I'm speculating here, that that was the</p> <p>12      precursor to M7.</p> <p>13      Q.   They say that this is --</p> <p>14      rephrase.</p> <p>15      They say that the valsartan</p> <p>16      is in accordance with ICH M7.</p> <p>17      Do you see that?</p> <p>18      A.   Yes.</p> <p>19      Q.   So based on this document,</p> <p>20      ZHP was applying ICH M7 as of July 14,</p> <p>21      2015, correct?</p> <p>22      MS. DAVIDSON: Objection.</p> <p>23      THE WITNESS: I'm sorry, but</p> <p>24      it doesn't say that.</p>



1 BY MR. SLATER:

2 Q. They're making a  
3 genotoxicity statement and they're  
4 representing that the valsartan complies  
5 with ICH M7.

6 That's what the document  
7 says, right?

8 A. It says that the drug  
9 substance valsartan manufactured by this  
10 is, to the best of our knowledge, in  
11 accordance with M7, yes.

12 Q. They then say, The reagents,  
13 intermediates and impurities susceptible  
14 of generating genotoxic impurities have  
15 been taken into account. No genotoxic  
16 impurities are present in the substance.

17 Do you see that?

18 A. Yes.

19 Q. In retrospect, that  
20 statement was incorrect, because we know  
21 that there were genotoxic impurities in  
22 the valsartan, correct?

23 MS. DAVIDSON: Objection.

24 THE WITNESS: In 2023 and in

1 post June 2018, yes, we know.

2 Pre June 2018, ZHP didn't  
3 know.

4 MR. SLATER: All right. I'm  
5 not going to ask any other  
6 questions at this point.

7 I'm reserving whatever  
8 minutes I have left. And  
9 depending on how many questions  
10 counsel asks, I will intend to  
11 continue to ask reasonable  
12 follow-up questions.

13 And I'm reserving all my  
14 rights regarding whether or not I  
15 need to ask for more time in the  
16 future.

17 So I'm handing it off to  
18 defense counsel.

19 MS. DAVIDSON: Thank you,  
20 Adam. I will just have very few  
21 questions. I need five minutes  
22 first.

23 VIDEO TECHNICIAN: Would you  
24 like to go off the record?

1 MS. DAVIDSON: Let's go off  
2 the record.

3 VIDEO TECHNICIAN: We're off  
4 the record at 6:25 p.m.

5 - - -

6 (Whereupon, a brief recess  
7 was taken.)

8 - - -

9 VIDEO TECHNICIAN: We're  
10 back on the record at 6:34 p.m.

11 MS. DAVIDSON: Great.

12 - - -

13 EXAMINATION

14 - - -

15 BY MS. DAVIDSON:

16 Q. Dr. Afnan, it's late in the  
17 evening. I just have a few very quick  
18 questions for you.

19 My first question is,  
20 earlier today there was some discussion  
21 of the DMF --

22 A. You froze.

23 Q. -- is that correct?

24 A. Sorry. You cut out.

1 Can you repeat?

2 MS. DAVIDSON: I went back  
3 upstairs. Okay. It's clearly an  
4 upstairs/downstairs thing. Can  
5 you guys hear me now?

6 BY MS. DAVIDSON:

7 Q. So I said that earlier today  
8 I believe there was some discussion of  
9 the DMF for the zinc chloride process,  
10 and you testified that the DMF is still  
11 active; is that correct?

12 A. The drug master file is  
13 still active, yes.

14 Q. Do you know whether there  
15 have been any changes to that drug master  
16 file over time?

17 A. Yes.

18 Q. And when I say do you know  
19 if there have been, maybe that wasn't a  
20 great question.

21 Have there been --

22 A. Yes.

23 Q. -- changes in the drug  
24 master file over time?

<p style="text-align: right;">Page 426</p> <p>1 A. Yes, there have been changes 2 to the DMF. 3 Q. Okay. My other question for 4 you was, earlier today we talked about a 5 WHO document. 6 MS. DAVIDSON: And can we 7 bring that document back on the 8 screen? Unfortunately, I don't 9 remember what exhibit number it 10 was. 11 We can either reintroduce it 12 or -- Chris, do you know what 13 document that was? The WHO 14 document, Chris Geddis, master of 15 the documents? 16 MR. SLATER: He sort of 17 checked out on this thing. He was 18 working on other stuff. 19 MS. DAVIDSON: He's not 20 here? 21 MR. SLATER: He's here, but 22 he moved on to some other work. 23 Exhibit-6. 24 MS. DAVIDSON: Okay.</p>	<p style="text-align: right;">Page 428</p> <p>1 everybody. 2 VIDEO TECHNICIAN: If 3 there's nothing further, the time 4 is now 6:37 p.m., this concludes 5 today's testimony from Dr. Ali 6 Afnan. We are now off the record. 7 - - - 8 (Whereupon, the deposition 9 concluded at 6:37 p.m.) 10 - - - 11 12 13 14 15 16 17 18 19 20 21 22 23 24</p>
<p style="text-align: right;">Page 427</p> <p>1 BY MS. DAVIDSON: 2 Q. Dr. Afnan, if you could -- I 3 believe you have Exhibit-6 in your files. 4 I just want to make sure you know which 5 document we're talking about. 6 A. Yes. It's the -- it's the 7 WHO document 2001. 8 Q. I just wanted to clarify, do 9 you -- looking at this document, do you 10 know when you first saw it? 11 A. Actually, I made a mistake, 12 I think, because it looks familiar. 13 This was presented in -- I 14 saw this after my report. This was 15 present in Dr. Bain's testimony as one of 16 the exhibits of her testimony. So I have 17 not seen it prior to writing my report. 18 MS. DAVIDSON: Those are my 19 only questions. 20 THE WITNESS: I apologize. 21 MR. SLATER: No other 22 questions. 23 MS. DAVIDSON: Enjoy your 24 dinner, Adam. Have a good night</p>	<p style="text-align: right;">Page 429</p> <p>1 CERTIFICATE 2 3 4 I, Amanda Maslynsky-Miller, Certified 5 Realtime Reporter, do hereby certify that 6 prior to the commencement of the examination, 7 ALI AFNAN, Ph.D., was remotely sworn by me to 8 testify to the truth, the whole truth and 9 nothing but the truth. 10 I DO FURTHER CERTIFY that the foregoing is a 11 verbatim transcript of the testimony as taken 12 stenographically by me at the time, place and 13 on the date hereinbefore set forth, to the 14 best of my ability. 15 I DO FURTHER CERTIFY that I am neither a 16 relative nor employee nor attorney nor 17 counsel of any of the parties to this action, 18 and that I am neither a relative nor employee 19 of such attorney or counsel, and that I am 20 not financially interested in the action. 21 22 Amanda Miller 23 Certified Realtime Reporter 24 Dated: February 10, 2023  (The foregoing certification of this transcript does not apply to any reproduction of the same by any means, unless under the direct control and/or supervision of the certifying reporter.)</p>

## ACKNOWLEDGMENT OF DEPONENT

I, \_\_\_\_\_, do hereby certify that I have read the foregoing pages, 1 - 428, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

---

ALI AFNAN, Ph.D.
DATE

Subscribed and sworn  
to before me this

It is imperative that you return the original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.

My commission expires:\_\_\_\_\_

Notary Public

## LAWYER'S NOTES

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[illegible]

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